American Society of Addiction Medicine

Submission to the Food and Drug Administration

Comments for Docket No. 95N-0253J and 95N-0253

December 29, 1995

Note: Binders 1 - 19 (the box is number 7) are the appendices to these comments. The contents of Binders 15 - 19 are listed in Tables 2 - 11 and in Table 14. Binder 8 is in two parts, 8A and 8B.

American Society of Addiction Medicine--ASAM

Docket No. 95N-0253J/ 95N-0253

Appendix-Box #7

Promotional Items and Books

4601 North Park Avenue
Upper Arcade, Suite 101
Chevy Chase, MD 20815

301-656-3920
fax: 301-656-3815

95N-253J

95N-0253

C 97
C58287

American Society of Addiction Medicine - ASAM
Docket No. 95N-0253J / 95N-0253
Appendix - Box # 7

	Item #
LORILLARD	
"Newport: Alive With Pleasure" free T-shirt with purchase	1
PHILIP MORRIS	
"Benson & Hedges Special Kings: Free Cap With Two Packs" (cap has "take the edge off" sewn onto it)	2
"Marlboro: Free Racing Cap With 3-Pack Purchase"	3
R. J. REYNOLDS	
"Camel: Genuine Taste Mission Kit" includes a mail offer for free packs, 2 enclosures and a tin (note: the kit is enclosed in its original envelope)	4
"Camel: Special Lights 100's" Carton enclosed in its mailing box	5
"Camel Motorsports Lighters: 2 Free With 2-Pack Purchase" box includes lighters and packs	6
"Camel: Free Cap With 3-Pack Purchase" box includes cap and packs	7
UST	
"Copenhagen Snuff: It Satisfies" tin	8
"oal Bandits: Free Playing Cards" mounted on a display card	9
MISCELLANEOUS	
"NASCAR Winston Cup 25th Anniversary Commemorative Book"	10
"Smoke: cigars, pipes, and life's other burning desires" : Volume 1, Number 1, (Holiday 1995)	11
Akehurst, B. C. : "Tobacco" (1981)	12
Tso, T. C.: "Production, Physiology, and Biochemistry of Tobacco Plant" (1990)	13

2048297262

PART A

Comment to

The Food and Drug Administration

Regarding

Docket No. 95N-0253J

Proposed Rule Analysis Regarding FDA's Jurisdiction Over Nicotine-Containing Cigarettes and Smokeless Tobacco Products

American Society of Addiction Medicine

4601 North Park Avenue
Upper Arcade, Suite 101
Chevy Chase, MD 20815

301-656-3920
fax: 301-656-3815

The preparation of this comment was supported in part by grant number 026766 from the Robert Wood Johnson Foundation

Comments on Analysis Regarding the Food and Drug Administration's Jurisdiction Over Nicotine-Containing Cigarettes and Smokeless Tobacco Products

General Observations

The American Society of Addiction Medicine agrees with the Food and Drug Administration that nicotine in cigarettes and in smokeless tobacco products is a pharmacologically active agent that causes addiction in a high proportion of users. Moreover, the evidence that the agency has presented in its analysis establishes that the nicotine in cigarettes and in smokeless tobacco products is a drug under the Food, Drug and Cosmetic Act because manufacturers of these products intend that the nicotine in these products affect the structure or function of the body.

It follows that cigarettes and smokeless tobacco products which contain nicotine are, themselves, nicotine delivery systems and that these products are both drugs and devices. The Society concurs with the agency's decision to regulate cigarettes and smokeless tobacco products that contain nicotine as nicotine delivery devices rather than use its drug authority to regulate them: these products cannot be made safe, and their sudden removal from the market would not be desirable.

"Tar-Centered" vs "Nicotine-Centered" Perspectives on Tobacco

From the early 1950s through about the mid-1980s, much of the public and scientific discussion about the problems caused by tobacco centered on the material in tobacco that directly caused illnesses such as lung cancer and heart disease. Scientific concerns in this era mainly focused on "tar" and the components of tar and whole cigarette smoke that were suspected of causing disease. Technical work which attempted to make cigarette smoking less hazardous was an official activity of the National Cancer Institute for much of the 1970s.

The tobacco industry participated in the public discussions of the toxicity of smoking in a variety of ways. For instance, the Tobacco Institute published a newsletter for physicians in the 1950s [B8, N1][1] which discussed the quality of the evidence that smoking did or did not cause disease. The research program of the Tobacco Industry Research committee at the time was focused on whether smoking caused lung cancer and other ills [B8, N2]. At the public relations level, reducing toxins was the watchword: filters, lower tar, and dilution through air vents were aggressively pursued between the early 50s and the early 1980s.

By the early 1980s, however, it was becoming clear to the general scientific community that the supposed toxin reduction that had been achieved was not making cigarettes substantially less dangerous. See, for instance, discussions in the Surgeon General's Reports of the 1980s, beginning with the 1981 report on "The Changing Cigarette," and concluding with the 1989 report which summarized 25 years of progress [B8, N3].

At the same time, the tobacco industry conducted active programs of research on nicotine pharmacology beginning before mid-century. These programs continued and accelerated in the 1950s and 60s. During this period, there was virtually no government-sponsored research on nicotine even though there was a large amount of government support for research on the epidemiology of tobacco use and disease consequences and on the biology of disease consequences of tobacco use.

The National Institute on Drug Abuse sponsored two symposia on nicotine in the late 1970s [B8, N4]. Taken together, these two volumes, neither of which reported work that had actually been supported by NIDA, describe nicotine use as a dependence process. The volumes are symposia reports, though. Their conclusions were not those of NIDA, much less those of the Public Health Service or the Department of Health and Human Services. Subsequent work, including research funded by NIDA, led, a decade later, to the conclusion by the PHS and by DHHS that nicotine was an addicting drug (see the 1986 PHS report on smokeless tobacco and the 1988 Surgeon General's Report on nicotine addiction).

---

[1] In this submission, appended material is collected into numbered binders and a box. The contents of these are listed at the back of the comments. In the text, appendices are referred to by binder (B#) and by number within each binder (N#).

Since the 1988 Surgeon General's Report, there has been a marked shift in perspective in the medical and the public health communities about nicotine. Tobacco use is more clearly understood as the production and the maintenance of nicotine addiction rather than as the provision of "tobacco pleasure" or similar vague terms.

At the same time, it is only in the past two years that it has become clear that the tobacco industry has long recognized that nicotine addiction is a central phenomenon in its business [B8, N5, pp 225-233]. Moreover, it is only with the recent publication of previously secret documents from within the industry and from new analyses of other materials such as patents that a coherent picture of the degree to which the industry has sought to manipulate nicotine content and delivery has become clear. This coherent picture is described in the agency's analysis and it leads to the conclusion that the manufacturers of cigarettes and smokeless tobacco products that contain nicotine intend that these products affect the structure or function of their customers' bodies.

Nicotine has long been recognized to play an important role in tobacco use. However, nicotine addiction was not focused upon as a public health problem until the past seven years. Although the tobacco industry has long had a deep understanding of nicotine and of how to insure that customers received the "right" dose, this knowledge, and the uses that the industry has made of it, have been concealed from public health officials until the past two years.

Since the early 1950s, the Food and Drug Administration has dealt with tobacco products on a case by case basis. From time to time, situations arose which led the agency to regulate one brand or another as a drug. In each case, the issue at hand was whether the agency was able to conclude that the manufacturer intended that the product function as a drug under the definitions set forth in the Food, Drug and Cosmetic Act. In the 1950s, the cigarette brands Fairfax and Trim were regulated as drugs. In the 1980s, Favor and Spectra were regulated as drugs, and Masterpiece was regulated as a food [B8, N6; B8, N7]. The agency used those parts of the definitions of drug and of food in the FDCA appropriate to the particular situations posed by these five products in making these determinations.

In the present case, the agency has examined whether nicotine-containing cigarettes and smokeless tobacco products fall under the FDCA. In reaching its conclusion, the agency has relied in part on newly available information that provides an understanding of manufacturer intent. The fact that the agency did not come to this conclusion about cigarettes and smokeless tobacco products in the past should have no bearing on the present case since information essential to the determination of manufacturer intent was not available to it until very recently.[2]

---

[2] Likewise, Congress has been in the dark about the deliberate intent of tobacco product manufacturers to deliver precise doses of nicotine to their customers and to produce specific pharmacological effects in them, including addiction.

The agency has been willing to consider whether tobacco products fall under the FDCA since at least 1952. The fact that it now has done so for two broad classes of tobacco product instead of for particular brands is a function of the evidence the agency has been able to examine.

The manufacturers of cigarettes and of smokeless tobacco products have long been successful in concealing their true intentions regarding nicotine. If what is now on the public record had been known in the past, FDA could have taken the steps it is only now taking much, much earlier. Had this been possible, many millions of lives might have been saved.

If the manufacturers of cigarettes and of smokeless tobacco products succeed in preventing FDA regulation by arguing, in essence, "You're too late, guys! You should have done this decades ago," as they have suggested in court filings which challenge the FDA proposal, these purveyors of the most dangerous consumer products in the country will be further rewarded for decades of concealment and disinformation. Their irresponsible behavior, which endangers the 60 million Americans who smoke cigarettes [B8, N8] and the one million young people who start to smoke each year, will continue unabated.

Until the Spring of 1994, the subject of whether members of the tobacco industry intended that their products affected the structure or function of the body was not examined in any Congressional hearing.

Advertising for Tobacco Products Suggests Intentions to Affect the Structure or Function of the Body

Over the years, advertisements for cigarettes and for smokeless tobacco products have included material that suggests that the manufacturers intend their products to affect the structure or function of the body. The presence of this material, which spans a period from at least the late 1920s to the present, raise questions about the depth of knowledge and understanding these companies have and have had about the pharmacology of nicotine and about the degree to which their products have been privately regarded as nicotine delivery devices. These questions can best be answered by the examination of a wide range of materials from the companies, as the FDA has done in its Analysis.

This section briefly reviews some tobacco product advertising which has, since the 1920s, implied an intention to affect the structure or function of the body. The advertisements mentioned in this section are presented in Binder #6.

Inhalation. [See ads at B6, N1 - B6, N28] A cigarette will only function normally if the nicotine in cigarette smoke is absorbed into the bloodstream so it can reach the brain. If cigarette smoke is merely puffed and held in the mouth before it is expelled, little nicotine is absorbed. Inhalation is the key to nicotine absorption from cigarettes, and there is no reason other than nicotine absorption for the consumer to inhale the smoke (see the 1988 Surgeon General's Report) [B8, N6; B8, N9].[3] Because of the low pH of cigarette smoke, little nicotine is absorbed from the mouth. Inhalation permits nicotine absorption from the lungs. Indeed, nicotine

---

[3] Representatives of the tobacco industry have pointed to the work of Jed Rose and Edward Levin as providing a view which is contrary to this. For instance, the abstract for one of their papers begins, "The satisfaction derived from smoking depends not only on the pharmacological effects of nicotine but also the sensory stimulation from smoke inhalation, particularly the tracheal 'scratch'" [B8, N10]. However, Rose and Levin regard the tracheal 'scratch' as a conditioned stimulus, that is, as a sensation which would have no reinforcing meaning for the consumer but for the accompanying pharmacological actions of nicotine, which Rose and Levin regard as the unconditioned stimulus [B8, N11]. The phenomenon of stimuli that are merely associated with drug ingestion developing reinforcing qualities is commonly observed with psychoactive drugs. Rose and Levin mention heroin as an example of another drug which has been shown to exhibit this phenomenon. Thus, the tracheal 'scratch' which arises from the inhalation of cigarette smoke is a sensation which has become paired with the absorption of nicotine into the bloodstream and the consequent effects of nicotine on the brain. People do not smoke for the 'scratch'; they smoke for the nicotine. The 'scratch' (related to "impact" discussed by a presenter at a BAT research/marketing conference held in Montreal in 1984 and discussed in the agency's analysis at 60 FR 41777, note 595) tells the smoker that nicotine is on its way to the brain and provides some indication of the relative dose which will shortly be coming (the "whole body sensation").

absorbed from the lungs reaches the brain more rapidly and with more immediate effect than that absorbed from the mouth. Moreover, cigarettes are designed to produce smoke of low pH which is perceived as milder and therefore as being easier to inhale.

Four Lucky Strike (American Tobacco Company) advertisements from the 1930s asked, "Do you inhale?" The copy for one continues, "'Everybody's doing it!' 7 out of 10 smokers inhale knowingly – the other 3 inhale unknowingly." The copy in the ads details the mildness of smoke from Luckies and the fact that the toasting process is "Your Protection – against irritation – against cough." This links protection from irritation to inhalation.

A Camel (RJ Reynolds) ad from 1931 instructs consumers on how to test the mildness of smoke from a Camel cigarette. "First, inhale the cool fragrant smoke of a perfectly conditioned Camel and note how easy it is to the throat." This text accurately indicates that sensations created by smoke in the throat only occur if the smoke is inhaled. If the smoke is merely puffed, it does not reach the throat.

In the 1940s, advertising for Philip Morris brand (Philip Morris) cigarettes included an extensive series that examined the question of inhalation. Headlines carried such claims as, "You can't help inhaling – but you can help your throat! Once again, inhaling cigarette smoke was being described as the normal, intended way to use cigarettes, and the benefit of the particular brand being advertised was that it produced less throat irritation. Were the smoke not intended for inhalation, throat irritation would not have been a concern.

Embassy (Lorillard) was an early king size brand. Ads for Embassy beginning in the early 1940s and continuing for about ten years promised that the consumer could "Inhale to your heart's content!" Again, the claim was linked to a promised mildness. These ads went further, though, assuring the consumer of "an extra margin of protection" from unspecified hazards.

Viceroy (Brown and Williamson), in one of its 1952 "health protection" ads, mentions, "The Nicotine And Tars Trapped by the Viceroy Filter Cannot Reach Mouth, Throat Or Lungs!" At the very least, this indicates an awareness on the part of Brown and Williamson that its consumers exposed their lungs to smoke when they smoked Viceroys. That is, Viceroy smokers also inhaled.

Inhalation is also mentioned in a Camel ad from 1951. Actress Anne Jeffreys describes the "30 day mildness test" she undertook for the brand and mentions inhalation of the smoke. This ad depicts the "T-Zone", which includes the mouth and throat, down past the larynx, which is where smoke is intended to travel. Smoke only reaches this far down if it has been inhaled.

Cigarette advertising became silent on inhalation by the mid-1950s after the Federal Trade Commission issued guidelines for cigarette advertising (see below).

However, occasional mentions of inhalation appeared in advertisements for cigars in the 1960s. The two examples date from the period shortly after the publication of the 1964 Surgeon General's Report, when cigar manufacturers were seeking markets among cigarette smokers who were frightened about the risk of lung cancer from smoking cigarettes. The White Owl ad mentions the fact that one does not have to inhale a cigar to "enjoy" it, while the Madison ad links the same fact to the ability of the little cigar to "Satisfy your smoking taste." These cigar ads, by making the point that inhalation is not necessary for cigars to function normally, drew a contrast with cigarettes, for which inhalation is necessary (see discussion of testimony before Congress in 1973 about the Little Cigar Act, below) [B8, N6].

Irritation. [See ads at B6, N29 - B6, N61] As described in cigarette advertising from the 20s through the mid-50s, the reduction of irritation is related to avoiding unpleasant sensations in the throat and to the prevention of coughing. Both of these advantages are only pertinent if the consumer inhales the smoke.

Lucky Strike (American Tobacco) ran an extensive series of advertisements based on the "It's toasted" theme. A brochure probably published in 1928 explains the issues involved and presents the results of surveys of physicians and dentists that support its claim [B6, N29]. Several ads ask the reader to "Consider your Adam's Apple!!" and showed a model pointing to the middle of her neck, where the benefit of mild smoke could only be appreciated upon inhalation.

Similarly, Liggett & Myers claimed that there was "Not a cough in a carload" of Old Gold cigarettes. Coughing would only be an issue were the smoke to be inhaled.

Philip Morris described Marlboro's "richer mildness" as being appreciated by "sensitive throats."

Kool (Brown & Williamson) "gives your throat a welcome change" from other cigarettes.

Pall Mall (American Tobacco) "lessens throat irritation!" The consumer could use Pall Mall to "Guard Against Throat Scratch".

Ads in a similar vein were put forward throughout the 40s and early 50s for Camel (RJ Reynolds) (where the T-Zone included the larynx and upper trachea), Philip Morris (Philip Morris), Raleigh (Brown & Williamson), Chesterfield (Liggett & Myers), and Old Gold (Lorillard).

Thus, all six major manufacturers of cigarettes once ran ads which had the theme of reduced throat irritation. Throat irritation was a problem only because of inhalation. Products designed for the oral absorption of nicotine did not need to worry about inhalation or about throat irritation. Indeed, cigar ads could instruct consumers that these products did not need to be inhaled to be properly used. The

terms "mild" and "mildness" frequently appeared in this context as well. The use of these latter terms in current cigarette advertising may continue to communicate this concept. Cigarette companies have never told customers that inhalation was a misuse of their products or that avoiding inhalation was the best way to avoid throat irritation.

The Federal Trade Commission guidelines, 1955. In 1955, the Federal Trade Commission issued a set of guidelines for cigarette advertising that put a stop to many of the overtly health-oriented themes in cigarette advertising [B6, N62]. After the FTC guidelines were published, references to reduced irritation and to inhalation disappeared from cigarette advertising.

Pharmacological actions of cigarette smoking. [See ads at B6, N63 - B6, N80] Cigarette advertising has included themes that are best understood as referring to the pharmacological actions of nicotine [See the 1988 Surgeon General's Report. In 1969, the Canadian tobacco industry suggested that smoking had a wide variety of beneficial pharmacological effects at B8, N12, especially pp 1632-1639].

The use of nicotine is associated with reduced appetite and with weight loss (see 1988 Surgeon General's Report). In the 1920s and 30s, American Tobacco ran a series for Lucky Strike based on weight control through smoking. The series pictured slim-featured models with a grotesquely obese "future shadow" cast behind them. "When Tempted, Reach for a LUCKY instead," ran a typical line.

In the 1930s, RJ Reynolds claimed, "CAMELS can literally relieve fatigue and irritability." The "Get a LIFT with a Camel" series promised that in smoking a Camel, "you will quickly feel your flow of natural energy being restored. That 'done-in' feeling drops away. Your pep and cheerfulness come flooding back." This is an accurate description of the stimulation many smokers experience from their cigarettes. It is an experience that arises from the pharmacological effects of nicotine.

In the same period, RJ Reynolds described the use of Camels as an aid to digestion. The advertisements claimed, "Camels make mealtime more pleasant – digestion is stimulated – alkalinity increased." The claims directly indicate that smoking affects digestive function in a positive way.

Lucky Strike (American Tobacco) made the claim, "Luckies' fine tobacco picks you up when you're low...calms you down when you're tense." This concept combines the common perception smokers have that cigarettes can lead to both stimulation and relaxation and refers to effects of smoking on the function of the body.

Explicit pharmacological appeals have been rare in cigarette advertising since the FTC guidelines were issued with one major exception. The advertising of cigarettes directed at women emphasizes weight control and thinness. These themes

directly deal with effects on the structure or function of the body. This has been discussed in a petition before the agency about cigarette brands targeted at women filed by the Coalition on Smoking OR Health. It is exemplified in this submission by three advertisements for various versions of the Virginia Slims brand of cigarette (Philip Morris).

In 1992, Philip Morris launched an extension of Benson & Hedges called Benson & Hedges Special Kings with a set of brand-related clothing that carried the theme, "take the edge off" [B6, N77 - B6, N79]. The phrase invites the consumer to relax, to calm down from a stressful state, promising this effect as the result of smoking one of these cigarettes. This, then, is an allusion to the relaxation that cigarette smoking can induce in a smoker, an effect that is mediated by the action of nicotine on the brain [B8, N9, pp 453-459] The phrase promises this benefit to the consumer and so promises an effect on the structure or function of the body.

Philip Morris received a trademark on "take the edge off" for use on t-shirts and caps in September 1994 [B6, N80]. In addition to photographs of "take the edge off" promotional material and a clothing catalog, a cap with this legend is included in the box of supplementary materials [B7, N2].

Satisfaction. [See ads at B6, N81 - B6, N102] "Satisfaction" is a state of well-being that tobacco products offer consumers.[4] (In part, the effect is produced by the relief of withdrawal symptoms.) It has been promised in tobacco product advertisements for decades and still is in the repertoire of ad claims. As discussed in the agency's Analysis and as revealed in Documents from the Brown & Williamson Corporation,[5] "satisfaction" refers to the pharmacological effects of nicotine on the brain [B8, N5, pp 225-233; B8, N9]. It is a promise that appears in a wide variety of advertisements for tobacco products.

Bull Durham (a RYO cigarette tobacco made by American Tobacco), Chesterfield (Liggett & Myers) ("They Satisfy"), and Kent (Lorillard) provide examples of the use of the term prior to 1970.

In the 70s and 80s, the following brands promised "satisfaction": Copenhagen (UST), Skoal (UST), Happy Days (UST), Chesterfield (Liggett & Myers), Real (RJ Reynolds), More (RJ Reynolds) ("I'm More Satisfied"), Salem (RJ Reynolds), Triumph (Lorillard), Camel Lights (RJ Reynolds), Barclay (Brown & Williamson), and Now (RJ Reynolds).

---

[4] "Pleasure" is another term used in tobacco product advertising which has pharmacological connotations in this context.

[5] The Brown & Williamson Corporation manufactures both cigarettes and smokeless tobacco [B8, N13], so material from B&W and from BAT speaks not only to whether the nicotine in cigarettes is a drug but also to whether the nicotine in smokeless tobacco products is a drug.

.In the 1990s, True (Lorillard) and Copenhagen (UST) have used the term.

UST has trademarked the phrase "It Satisfies" as a signature tag line for Copenhagen [B6, N102]. In fact, the use of the phrase is also trademarked for use on promotional clothing for the brand (see Table 1)[B6, N102]. Each package of Copenhagen carries the legend, "It Satisfies" on the lid [B7, N8].

Filters and low tar. [See ads at B6, N103 - B6, N110] Filtered cigarette brands have been largely promoted as ways to reduce the risks of smoking [B8, N3; B8, N6; B8, N14]. The same is true of so-called low tar brands. However, the only plausible reason these innovations were needed in order to offer the public a hope of reduced risk of lung cancer and heart disease from smoking was that it was intended that consumers inhale the smoke from cigarettes. This, in turn, was necessary only because of the need to inhale in order for the consumer to rapidly absorb a substantial dose of nicotine into the bloodstream. Thus, advertisements for filtered cigarettes and for low tar brands, and the products themselves, can largely be seen as offering reassurance that the risks associated with inhalation (e g, nicotine ingestion) have been reduced.

For purposes of the present discussion, it matters not that these promises of relative safety have been, for all practical purposes, unmet. What matters is that the manufacturers have, essentially, told their customers that they have been working hard to make it less hazardous for consumers to inhale. This would seem to reflect an intention to affect the structure or function of the body. After all, since inhalation sets up the lions share of toxic consequences from smoking, an obvious remedy would seem to be to engineer the cigarette so that its smoke was unlikely to be inhaled. The fact that the manufacturers have instead chosen to provide filtered and low tar brands (with accompanying claims of "mildness") strongly suggests that the manufacturers intend for their customers to inhale cigarette smoke. If inhalation is intended, then so is the absorption of nicotine.

The appendix includes a small selection of ads for filtered brands and for low tar brands [B6, N103 - B6, N110]. The implied disease prevention claims for low tar brands have been more fully discussed in the petition on low tar brands that has been filed with the agency by the Coalition on Smoking OR Health. However, that petition focused simply on the disease prevention aspects of these brands and not on the underlying assumptions about nicotine ingestion contained in this cigarette engineering strategy.

Several of the low tar ads, for Vantage (RJ Reynolds) and for True (Lorillard), speak with unusual directness about there being "problems about smoking" [B6, N108; B6, N109; B6, N110]. The offered solution to the health concerns that the speakers in these ads are worried about is the low tar smoke. Advertising for low tar brands dominates cigarette marketing expenditures. The Federal Trade Commission has reported that 1993 advertising expenditures for low tar brands accounted for 65.9% of all cigarette advertising expenditures [B6, N111].

Advertisements for cigarettes and smokeless tobacco raise questions about the manufacturers' intentions that call for further investigation. The advertisements reviewed here point to an intention to affect the structure or function of the body. In other recent cases, the agency has been faced with marketing materials for tobacco products which have indicated manufacturers' intentions regarding drug effects of their products [B6, N112; B6, N113].

In making its decisions to regulate Favor Smokeless Cigarettes and Spectra brand cigarettes as drugs, the agency relied on a variety of materials in addition to labeling and promotional materials. These included SEC filings, patent applications, and a prospectus for a stock offering.

In the present situation, in which the agency is considering whether the nicotine in cigarettes and smokeless tobacco products is a drug, advertising for these products raises questions about the intention of the manufacturers to affect the structure or function of the body. Just as the FDA did in the cases of Favor and of Spectra, the agency should base its decision in the present case on all the information which comes to its attention.

Public Comments from the Tobacco Industry About Nicotine

In 1895, Pierre Lorillard, Jr., the President of P. Lorillard, wrote,

> It seems almost incredible that tobacco, the dried product of a common herb, possessing the properties of a narcotic stimulant, and in no way necessary for man's sustenance, should have from its first introduction progressively increased in consumption wherever used throughout the habitable globe; that, despite the opposition of the combined powers of the church, the state, and the moralist to its use, its consumers being the subject of ridicule, persecution, and even mutilation, and itself an object of universal taxation, it furnishes at the present time not only one of the largest staples of commerce, but provides as well one of the leading manufacturing industries of mankind [B8, N15].

This unusually frank assessment was written more than a decade before the first federal regulation of drugs came into effect and more than forty years before the FDCA included a definition of "drug" that relied on manufacturer intent rather than merely on listings in official compendia.

In recent times, tobacco company officials have usually been more circumspect in their public descriptions of the pharmacological actions of tobacco products. Table 2 contains quotations from tobacco company executives and statements at Congressional hearings in 1994 and at the FDA's Drug Abuse Advisory Committee meeting in August 1994 which considered whether nicotine was addicting [B15, N1 - B15, N6]. These have been selected to reflect the official opinions about nicotine held by the tobacco companies.

Prominent among the statements are those that declare nicotine to not be addicting, that cigarettes contain nicotine only because it occurs "naturally" in tobacco, that nicotine is not controlled or manipulated, and that nicotine is in tobacco for taste and flavor. There is an emphasis on the ways non-pharmacological aspects of smoking contribute in important ways to the experience of smoking. These officials point out that the nicotine content in finished products is lower than that found in the raw materials.

At the same time, these officials and official statements indicate that nicotine produces "pleasure" and "enjoyment" from smoking, that it can have "a mild pharmacological effect," and that someone who stops smoking can experience "some symptoms of withdrawal."[6]

[6] Contrast these sentiments with those expressed in a 1980 internal memorandum within Philip Morris:

The impressions conveyed by these industry statements, apart from the ones that describe pharmacological actions of nicotine, do not stand up to close inspection.

There is no doubt that nicotine regularly causes addiction in a high proportion of people who regularly ingest it. Industry officials try to hide behind a definition of addiction that differs from the one in general use. Industry spokespersons have emphasized that nicotine does not cause intoxication, and that this is a defining feature of addiction. It is not. Addictions are recognized clinically by loss of control over use and continued use despite problems. Nicotine fulfills this definition. Besides, if the dose is high enough, nicotine causes intoxication.

The industry's insistence that tobacco leaf is a "natural" product is true only in a very narrow sense. The impression that the term communicates, that the presence and quantity of nicotine in the tobacco leaf used in manufacturing processes is an accident of nature is a myth (see below). Even so, and perhaps to an even greater extent, marihuana leaf is also a "natural" product, but no one claims it is not a drug in the manner it is generally consumed. Indeed, not only is marihuana leaf a drug, it is a class I controlled substance.

Tobacco product manufacturers exert an enormous amount of control over the amount and form of nicotine in their final products, as demonstrated in the agency's analysis and in this submission.

While an abundant and still-burgeoning literature on nicotine pharmacology has accumulated over the past 50 years, much of it supported by tobacco industry sources, there is no literature on nicotine as a flavoring agent. Were taste and flavor actually the central purpose of nicotine in tobacco, surely there would have been at least some sponsored research on the subject. ASAM is not aware that there has been any published study on the taste or flavor of nicotine.

It is true that the smoking experience includes many non-pharmacological elements and that these elements contribute to the reinforcing qualities of smoking. However, as mentioned above, these non-pharmacological elements function as conditioned stimuli; nicotine's effects on the brain remains the unconditioned stimulus [B8, N10; B8, N11]. Without the accompanying CNS actions of nicotine, the tamping of the cigarette before lighting and the throat "scratch" would not have the same ability to soothe, relax, or help focus attention.

The situation is exactly analogous to the common experience of many people who are addicted to heroin. Heroin is the specific substance which, when delivered to the brain, will relieve withdrawal and produce pleasurable feelings. However, the

---

Nicotine is a powerful pharmacological agent with multiple sites of action and may be the most important component of cigarette smoke. [B8, N16]

heroin-addicted person engages in a stereotyped ritual of drug seeking, drug finding, drug purchasing, drug preparation, and drug injection before the heroin enters the bloodstream and finds its way to the brain. It is a common experience that withdrawal relief begins, not with the arrival of heroin in the brain, but earlier in the sequence. The closer the person comes to delivering heroin to the brain, the more symptoms abate.

If heroin were not psychoactive, the person would not have learned the ritual sequence in the first place. If the person switched from heroin to lactose as the substance being injected, the ritual would rapidly lose its value. The situation with nicotine in cigarettes is precisely analogous. People who use tobacco products build up rituals around nicotine ingestion and experience sensations in the process of using tobacco that become valuable to them. However, these rituals would not exist, and the sensations would be of no value, but for the associated delivery of nicotine to the brain.

The "satisfaction from smoking" [B15, N4, p 42] depends wholly on nicotine's CNS effects. But for these, there would be no subjective benefit from the irritation cigarette smoke causes in the throat. The pretense that satisfaction is not based on nicotine pharmacology is contradicted by private industry statements [B8, N5, pp 225-233] and by patents (for instance, a 1971 patent filed by Philip Morris describes satisfaction as resulting from delivering a consistent amount of physiologically active nicotine to the consumer [B8, N9, p 431]).

A somewhat different perspective on nicotine and on smoking was once expressed by officials representing the cigar industry. In 1973, Congress considered (and eventually passed) a bill that banned advertising on electronic media for brands of little cigars, which are generally packaged like cigarettes. During the hearings held in the House on this issue, several witnesses from the cigar industry sought to differentiate their products from cigarettes [B9, N1]. In doing so, they expressed views on nicotine and on smoking that conform to the conventional understanding of these things and which differ from the positions taken by cigarette company officials.

One of the things RJ Reynolds did after cigarette advertising was banned from electronic media in 1971 to overcome the adverse effects of the restriction (in addition to developing sports sponsorship for its brands and in addition to moving large amounts of money into billboards and into print media) was to introduce a new product, Winchester, a "little cigar", and to advertise it on television. Winchester, which was criticized by the cigar industry as being more cigarette-like than other products in the category, rapidly came to dominate the market [B9, N2]. Lorillard began to advertise its little cigar brands on television as well. Senator Frank Moss, who had been the main sponsor of the broadcast ad ban, successfully called upon RJR and Lorillard to voluntarily withdraw their television ads for these products. However, the Consolidated Cigar Corporation did not go along with this. Rather, it went ahead with plans to advertise its new brand, Dutch Treats, on television.

On May 22, 1973, E. W. Kelley, Chairman of Consolidated Cigar Corporation, testified before the House Commerce Committee about the proposed legislation. In his testimony, Mr. Kelley drew a number of distinctions between cigarettes and little cigars. Pertinent to the present discussion, Mr. Kelley said,

> We agree that *consumers have the right to know what they are buying* and that Congress has the responsibility to protect the public's health. We also believe that *manufacturers of consumer products should be mindful of their social responsibilities.*
>
> It is in this connection that *we contend that little cigars are a less hazardous alternative to cigarettes.* There is no evidence that little cigars are as harmful to health as cigarettes. It is important to note that the various Surgeon General's reports over the last several years have consistently stated that cigars are relatively a safer smoking product from a health standpoint. We, therefore, contended that the imposition of restrictions such as now proposed, without full and complete scientific basis, may be harmful, not only to the cigar industry, but also to the cigarette smoker who might, otherwise, switch to a safer smoking alternative. ...
>
> Many public and private health officials have called for a safer alternative to cigarette smoking for those who will not give up the cigarette habit. The American cigar industry has provided this safer alternative for many decades by producing cigars. Despite this, cigarette sales are increasing more rapidly than cigar sales. ...
>
> The Consolidated Cigar Corp. considers it important to attempt to provide this safer alternative in a way which would be more acceptable to cigarette smokers than large cigars – using, however, the same strict product guidelines which we have imposed on ourselves for larger cigars. ...
>
> We make no pretense of being completely altruistic; there is a coincidence of interest here; if we are successful, we stand to gain economically, but *the smoker stands to gain healthwise.*
>
> We believe we have provided an alternative with Dutch Treats by Dutch Masters. ...
>
> *Even when inhaled, little cigars are less harmful than cigarettes.* At the same time we are aware that no smoking product is completely free of all health risks, and that to take advantage of the improvements we believe to be inherent in our new product, smokers will have to change their smoking habits. *They must learn that inhalation is not necessary to obtain smoking satisfaction.* They must become

> accustomed to a new kind of smoking experience. ...
>
> Much of the criticism of little cigars has been based on opinion, not fact. *It is claimed, for instance, that little cigars will be inhaled like cigarettes. The fact is, they are inhaled less than cigarettes and to a lesser extent.* (emphasis added) [B9, N1, pp 28-29]

Later in his testimony, Mr. Kelley described the technical differences between cigarettes and cigars. Among the major differences was smoke pH and nicotine availability:

> The smoke from the finished cigar should have a pH of 6.16 and above. *Such a pH level is the break point at or above which inhalation is unnecessary to obtain a nicotine effect.* This further distinguishes the smoke of little cigars from the smoke of cigarettes.
>
> You will note that the guidelines specify a pH of 6.16 and above for little cigars. That is our guideline. In an article by Dr. Fred Bock, of the Orchard Park Laboratories, and submitted by Senator Frank Moss for the Congressional Record, it is suggested that the pH factor be not less than 6.3 to insure that little cigars have a distinctly higher alkaline base than cigarettes.
>
> We at Consolidated also believe that the higher the pH factor the greater qualitative distinction there is between little cigars and cigarettes. Our Dutch Treats little cigars are well beyond our guidelines of 6.16 and Dr. Bock's suggested 6.3. (emphasis added) [B9, N1, p 30])

Robert N. DuPuis, a former head of research for Philip Morris and a consultant to Consolidated Cigar, described for the committee the differences in pH of cigarette smoke and smoke from Dutch Treats. He specifically mentioned that, because of the higher pH of cigar smoke, inhalation was not necessary for nicotine absorption.

> The result of importance to the smoker of little cigars made from fermented tobacco is that this smoke is unpleasant to inhale, and is not inhaled to the same extent as American cigarette smoke. ...
>
> Dutch Treats start out [with a] neutral [pH] and ended up even more alkaline. This is characteristic of cigar tobacco and the average pH is not less than 7.
>
> To the smoker of our little cigars, this means that:

> Inhalation is unpleasant and at a substantially lower level than that of cigarettes, and
>
> *Since nicotine in little cigars can be absorbed more readily without inhalation, the little cigar smoker obtains the nicotine effect which he desires by smoking less and by avoiding inhalation, thus fulfilling the need for a less hazardous form of smoking.* (emphasis added) [B9, N1, p 35][7]

This testimony to Congress in 1973 from Consolidated Cigar Corporation officials establishes that inhalation is necessary for cigarette smokers to obtain the nicotine effect, that the nicotine effect is what smoking satisfaction is all about, and that the absorption of nicotine (not its "scratching" the throat) is responsible for the nicotine effect.[8]

The President of the General Cigar Co., Edgar Cullman, also testified at this hearing. General Cigar is a subsidiary of Culbro, a Cullman family company. Mr. Cullman's brother, Joe Cullman III, was the CEO of Philip Morris at the time. Edgar Cullman's testimony is notable for a mention of concerns consumers have about the health risks of smoking.[9] His company made Tiparillos, whose advertising featured the question, "Should a gentleman offer a lady a Tiparillo?"

> Those small cigars [such as Tiparillo] made in a traditional way with wrapper binder and filler are cigars that people have smoked with the idea they are safer [than cigarettes]... .[B9, N1, p 85]

Finally, in 1969, the Canadian Tobacco Manufacturers' Council presented an extensive analysis of the risks and benefits of smoking to the Standing Committee on Health, Welfare and Social Affairs of the Canadian House of Commons. The submission is notable for the degree to which it relies on pharmacological research to explain the supposed benefits of smoking. This shows that Canadian cigarette makers, at least, understood the benefits of smoking in terms of the effects of nicotine on the structure or function of the body [B8, N12, pp 1538, 1580, 1587, 1632-1639, and 1650-1651].

---

[7] Alan Cornell, vice-president of research and development at Consolidated Cigar, testified at this hearing about the degree to which cigarette smokers inhaled smoke from little cigars [B9, N1, p 39-41]. While they inhaled less, inhalation was still quite common. This point was also made in an article included in the hearing record from the *Lancet*, a major British medical journal. All cigarette smokers tested who switched to cigars inhaled the smoke from their cigars [B9, N1, p 97].

[8] Dutch Treats brand little cigars are still on the market.

[9] Mr. Cullman refers to little cigars in his testimony as being "cigarette-type" products [B9, N1, p 81].

Was Pierre Lorillard, Jr. right? Is tobacco a "narcotic stimulant?" Whether or not it is, tobacco company officials know that nicotine is absorbed and that it causes pharmacological effects in the body. Some industry officials have described these effects as those which consumers seek from tobacco products. Moreover, as the FDA has described in its analysis, the industry behaves as though it believes this is so.

Additional Material Supports the Conclusion that the Manufacturers of Cigarettes and Smokeless Tobacco Products Intend that their Products Affect the Structure or Function of the Body

The FDA has presented a compelling and thorough analysis of the industry's intentions with regard to nicotine. The purpose of this and the following sections of this comment is to supplement the agency's analysis by providing FDA with material which generally supports the analysis it has done. The material in this section is discussed only briefly, but the articles cited are contained in the appendix.[10]

Inhalation. Reports of research funded by the tobacco industry or conducted in its laboratories along with other materials show that the cigarette industry has long been aware that its customers usually inhale cigarette smoke. Furthermore, the industry has known that inhalation exposes tissues to poisons from tobacco smoke which result in increasing the risk of disease: An internal document from BAT, written in 1974, declares, "Without inhalation smoking will present negligible health risks." [B16, N13]

Despite the fact that inhalation is the proximate reason that the cigarette is associated with many serious illnesses, cigarette makers have never discouraged the practice. They have not designed cigarettes so that inhalation was difficult. Instead, they have gone the other direction, taking steps to assure customers of *mildness* and *reduced* irritation.

The importance of inhalation to normal cigarette use, and the fact that intended cigarette use means nicotine absorption into the bloodstream, is strongly suggested by the inhalation experiment RJ Reynolds conducted and reported in its monograph, *New Cigarette Prototypes that Heat Instead of Burn Tobacco* [B9, N3]. In this experiment, RJR sought to compare how well the new device functions as a cigarette. The test chosen is a comparison of nicotine absorption between the new device and a cigarette. The essential function of a cigarette, then, seems to be to deliver nicotine to the lungs for absorption into the bloodstream.

Table 3 lists some publications from the cigarette industry or from industry-supported researchers that indicate an awareness of inhalation as the normal way cigarettes are consumed. The listed papers, which date from the mid-1930s through the 70s, are included in the appendices [B16, N1 - B16, N22].

[10] Some of the material is in the form of handwritten notes by Dr. S.J. Green, who directed research and development at BAT in the 1970s. Table 14 provides a listing of documents which, taken together, confirm that the handwritten material was by Green.

In addition, the Council for Tobacco Research supported an extensive research program on cigarette smoke inhalation at Microbiological Associates in the 1970s and 80s at a cost of more than $10 million. These studies were summarized in a monograph which was published in 1983 [B9, N4]. These are but a small sample of the many studies of inhalation that the industry has supported over the years. Were inhalation unnecessary for the normal functioning of a cigarette, none of this elaborate, expensive work would have been necessary.

Irritation. Irritation is mentioned not uncommonly in industry-associated literature in a context which indicates that irritation is a necessary component of the smoking experience (Table 4, [B17, N1 - B17, N3]). As discussed in the advertising section, irritation is produced in the throat as an accompaniment to inhalation.

Other Adverse effects of smoking. Table 5 summarizes industry-related statements that reflect an awareness of inhalation being related to problems such as lung cancer and losses in pulmonary function. The materials abstracted here are included in the appendices [B16, N22; B17, N4 - B17, N8].

Nicotine delivery and compensation. Table 6 provides examples of industry-related comments that indicate an interest in the delivery of nicotine to the consumer and a concern with compensation effects as tar and nicotine deliveries are lowered. The material abstracted in the table is included in the appendices [B16, N4; B16, N11 - B16, N13; B16, N19; B16, N22; B17, N2; B17, N3; B17, N7; B17, N8; B17, N9 - B17, N23].

Manufacturing and processing. Table 7 describes some industry-associated comments that relate to manufacturing and processing issues [B18, N1 - B18, N6]. Nicotine is a major concern in product design.

Pharmacological effects. Table 8 presents some industry-associated comments on the pharmacology of nicotine and of tobacco use including some comments about satisfaction [B16, N3; B16, N8; B16, N19; B16, N22; B17, N3; B17, N7; B17, N 10; B17, N15; B17, N16; B17, N23; B18, N7 - B18, N10; cites:...]. There has long been an awareness of nicotine's role in producing pharmacological effects, and often nicotine is described as the reason people ingest cigarette smoke. A detailed discussion was published in JAMA last Summer that describes the perspectives Brown & Williamson and BAT have had on nicotine as a pharmacological agent [B8, N5, pp 225-233].

The Wall Street Journal recently carried a story about an analysis of nicotine's role in tobacco use that was compiled by an executive at Philip Morris [B9, N5]. A copy of this report, as posted by the *Journal* on the Internet, is included in the appendix [B9, N6].

Addiction. Table 9 provides some references to addiction from industry-related materials which supplement those mentioned in the FDA's analysis. The referenced material is included in the appendices [B16, N8; B16, N17; B16, N18; B16, N20; B17, N3; B18, N11 - B18, N15].

Is Tobacco a "Natural" Product?

Spokespersons for the tobacco industry, in denying that the industry intends that its products affect the structure or function of the body, often refer to tobacco as a "natural" product and the nicotine in tobacco as being present whether they want it there or not. Industry statements have emphasized that there is less nicotine in finished cigarettes than in the raw materials that come into the factories [B9, N7]. This section will examine these industry positions.

The chief background materials for this discussion are papers from a symposium series, *Recent Advances in Tobacco Science*, and two textbooks that describe agronomic practice related to tobacco. Some key material from *Recent Advances* is summarized in Table 10 and the references articles are included in the appendices [B19, N1 - B19, N3]. The *Recent Advances* series is based on symposia presented annually since the 1970s at the Tobacco Chemists Conference. Copies of the textbooks, by B. C. Akehurst and by T. C. Tso, are included in the appendix [B7, N12; B7, N13]. The author's preface to Tso's book indicates that it was produced as a result of "generous support" from Philip Morris.

Tso sets the tone for this discussion in the opening paragraph of the first chapter in his book:

> All variables in tobacco plant, leaf, and smoke are interrelated. The objective of this chapter is to stress the concept that no step of tobacco operation from seed germination to smoke delivery can be isolated. [B7, N13, p 3]

The chapter ends on a similar note.

> In summary, information presented in this chapter demonstrates clearly that every operational step – from the breeding of a single seed, to the last puff of cigarette smoking – are interrelated. Technical modification can only alter or improve the available material at any given step. To achieve a final product of true quality for the consumer, a total effort from all concerned is crucial. And, only through the understanding of this concept, can one realize the importance of each step of the operation, and thus work toward a better product, based on the knowledge available to us. [B7, N13, pp 29-30]

From seed to smoke.

Tso describes nicotine as the "characteristic product" of tobacco [B7, N13, p 41] and he makes it clear that the reason nicotine is important is because of its pharmacological actions:

> Tobacco usage is primarily due to the stimulant effect of nicotine. Leaf composition is related to smoke components. By inhaling, it takes only 7 seconds for nicotine absorbed through the lungs to reach the brain. [B7, N13, p 427].

Akehurst also regards the absorption of nicotine from the lower respiratory tract with its resulting "physiological effect which derives from nicotine" as an essential part of the smoking experience [B7, N12, p 644].

Neither Akehurst nor Tso describe nicotine as making positive contributions to taste or to flavor.[11]

The following information is relevant to understanding whether the tobacco leaf in tobacco products is a "natural" product.

> The tobacco plant of commerce, *Nicotiana tabacum*, is not found in nature. It is thought to be a hybrid of two wild species, but it only exists as a domestic, cultivated plant [B7, N13, p 195].
>
> As described in both textbooks and in the *Recent Advances* series, nicotine production is genetically determined. Only certain strains of tobacco seed are used in agricultural production. Guidelines developed in concert with the cigarette industry require a certain *minimum* level of nicotine in new tobacco strains for those strains to be included in the government-supervised price support program [see B7, N13, p 20 and B7, N12, p 80].
>
> Every aspect of tobacco cultivation has been examined, and is in part chosen, for its effect on nicotine production. The reference material details the impact of spacing, fertilization, harvest timing, and other decisions which farmers must make. An unusual agronomic practice, topping (the removal of the flowering head from the growing tobacco plant), functions to *increase* nicotine levels in the leaf [B7, N13, pp 96-7; B7, N12, p 70]. Similarly, suckering is done by hand or, more commonly, by chemical means, to counter the axial bud growth that topping stimulates. Suckering is necessary to achieve the full benefits of topping.
>
> While nicotine levels decline somewhat in curing and in aging of tobacco leaf[12] [B7, N13, p 131], it is clear that the nicotine levels have been

---

[11] Tso describes techniques to reduce nornicotine content, perhaps because nornicotine contributes to tobacco-specific nitrosamine formation without contributing much to the pharmacological activity of the end product.

[12] Aging is usually accomplished in the warehouses of tobacco product manufacturers. Tobacco company spokespeople have not been specific about where in the process nicotine is lost in the course of the travels tobacco leaves make through their warehouses and factories. It may be that the reference is to the subtle decline in nicotine content that occurs during aging. Whatever these statements refer to, though, it is certain that, as detailed in the agency's analysis and in the appendices here, the finished products that come from these factories have controlled, desired, and intended contents of nicotine.

> *raised* by other practices. Moreover, the curing and aging processes are necessary to transform fresh tobacco leaf into a palatable form. Proper curing requires the following of precise guidelines for the production of an acceptable finished product. That is, its success is highly dependent on the skill of the farmer. It would not happen in a commercially useful manner were it not for a high degree of specific, directed human intervention.

In summary, agronomic and post-harvesting practices for tobacco cultivation are highly developed and are guided by sophisticated research. The term "natural," in this case, does *not* mean "without deliberate, goal-directed human intervention." The goal towards which tobacco cultivation, curing and aging are driven is the production of palatable tobacco leaf which contains a desired level of nicotine.

The case of tobacco and nicotine is exactly analogous to that of traditional botanical drugs. Quinine, digitalis, and morphine, as well as many other valuable medicines, were not only found originally in natural products (*Cinchona* bark, foxglove leaf, and opium poppy seed pod), they were used in their natural states. As the chemistry and pharmacology of these drugs came to be better understood, extraction and purification procedures developed which permitted the packaging of quinine, digitalis alkaloids and morphine as chemically pure substances for use as drugs. The botanical forms, bark, leaf and the latex from the seed pod, were themselves drugs, but they were bulky, inconvenient and not as well standardized as the pure chemicals.

As tobacco product manufacturers have developed a more and more sophisticated understanding of nicotine pharmacology, they have developed (and used) techniques which permit improved control over nicotine content and delivery in their products. The range of techniques available to them ranges, as Dr. Tso indicates, from seed to smoke. The one thing they have avoided doing, the thing which would most easily identify them as purveyors of a drug, is the step that the makers of quinine, digitalis and morphine did long ago: they have avoided offering their product, nicotine, in a chemically pure form. This has given them the ability to pretend that nicotine is not their product, but that tobacco is, and that nicotine is just accidentally present in the product. However, this pretense has dissolved with the public availability over the past two years of previously secret documents and with the analysis that the FDA has done of the industry's intent.

More than 25 years ago, D. J. Wood, a scientist employed by BAT, wrote,

> The presence of nicotine is the reason why the tobacco plant was singled out from all other plants for consumption in this rather unusual way.
>
> Nicotine has well documented pharmacological action. It is claimed to have a dual effect, acting both as a stimulant and a tranquilliser. It

is believed to be responsible for the "satisfaction" of smoking, using this term in the physiological rather than the psychological sense. [B5, N56, document 1184.02, p 7]

Tobacco is among the most extensively studied and best understood plants in the world. The results of this research have been used to shape agricultural practice, post-harvest handling of tobacco leaf, and the steps which are taken in tobacco product production once the agricultural product is in a warehouse or a factory. The FDA's analysis shows that, as used in products such as cigarettes and smokeless tobacco products which contain nicotine, tobacco is a botanical drug.

Technical Notes on Agency's Analysis of FDA's Jurisdiction

At several places in the analysis and the proposal, the agency cites documents from two Canadian companies, Imperial Tobacco and RJR Macdonald. Not only are the two related to US companies (Imperial is a subsidiary of BAT just as is Brown & Williamson, and RJR Macdonald is a wholly owned subsidiary of RJ Reynolds), but both also sell cigarettes in the United States. A listing in the appendix of cigarette brands available in the US indicates that Canadian brands such as Export A (RJR Macdonald) and DuMaurier (Imperial) are available for purchase in the United States through Kretek Imports, Inc. [B9, N8].

While American Brands has sold the American Tobacco Company to Brown & Williamson, American Brands still owns Gallaher Tobacco Limited in the United Kingdom. Silk Cut, a Gallaher brand, is sold in the United States through James B. Russell, Inc. [B9, N8].

60 FR 41517. Some of the evidence the agency uses to conclude that the nicotine in smokeless tobacco products is a drug has been published recently in a series of articles in *Tobacco Control.* These are included in the appendix along with an article from JNCI which reports on the nitrosamine levels found in moist snuff sold in the United States [B9, N9].

In addition, the agency should note that Brown & Williamson is a manufacturer of smokeless tobacco products (Bloodhound, B&W Sun Cured, Red Juice, John Henry, Tube Rose) as well as cigarette tobacco (Bugler and Kite) [B8, N13]. This means that information the agency has from Brown & Williamson and BAT on nicotine and on these companies' intentions regarding effects of nicotine on the body is directly relevant to a consideration of whether the nicotine in smokeless tobacco products (and that in cigarette tobacco) is a drug.

60 FR 41563. The irritant effect of nicotine in the throat helps consumers judge the dose of nicotine in the inhaled smoke. In addition to the references cited by the agency, Rose and Levin have written about this phenomenon elsewhere [B8, N10; B8, N11].

60 FR 41649. The agency references BATCO research documents to establish that the tobacco industry has the capability to measure nicotine absorption. RJ Reynolds has similar capabilities. This is demonstrated in its monograph on Premier, *New Cigarette Prototypes that Heat Instead of Burn Tobacco*, especially in the section that details the experiments comparing nicotine uptake after smoking prototypes of Premier and that following the smoking of a cigarette [B9, N3]. It is also apparent in the report presented by RJ Reynolds scientists at the December 1994 meeting sponsored by the National Cancer Institute on tar, nicotine and carbon monoxide deliveries from cigarettes [B10] as well as in other publications from this research group.

60 FR 41712. JC Leffingwell, quoted on this page, worked for RJ Reynolds.

60 FR 41752. The industry concern that antagonists might be developed to nicotine and that these drugs might pose challenges for cigarette companies may have been brought into focus by a presentation Murray Jarvik gave at a January 1972 research conference sponsored by the tobacco industry [B9, N10]. In his presentation, Jarvik described some early clinical work with a nicotine antagonist and clearly held out the hope that this class of drug might have clinical utility in helping people stop smoking. The BAT research report that describes work on analogues defensive research against antagonists was written later in the same year.

60 FR 41759. In footnote 545, the range of values given for acetaldehyde in cigarette smoke should be 400-1,400 ug.

60 FR 41763. In footnote 556, reference is made to "spray dried tobacco." This is actually a tobacco extract and not tobacco at all. The term is a neologism that RJ Reynolds developed to give the impression that this extract was tobacco. It is a similar rhetorical device to calling the paper made from tobacco scrap "reconstituted tobacco."

The way Premier worked is described as "heating rather than burning tobacco." Actually, the aerosol generator and most of the nicotine were contained on the alumina beads in the capsule. Premier worked by heating these beads, not by heating tobacco.

60 FR 41785. The number of adolescents using cigarettes is actually 4 million, not 3 million, according to figures released by SAMHSA in September 1995 [B8, N8], and the rate of smoking has been rising among high school students for the past several years, according to the Monitoring the Future survey from the University of Michigan [B8, N11].

Appendices

Appendix 2, "Corporate Relationship Between British-American Tobacco Co. and Brown & Williamson Tobacco Co.," details the interactions among scientists and executives for these companies as revealed in documents from B&W. These documents are included with this submission in an easily searchable form as a CD-ROM published by the University of California [B5, N56]. The agency might also note that Brown & Williamson functions as a cigarette manufacturer for BAT. Cigarettes made for export by Brown & Williamson (including such brands as Lucky Strike, Kent and Kool) are sold outside of the United States through BAT distribution channels.

In **Appendix 4**, "Bibliography of Industry-Funded Research," the agency lists research reports on nicotine known to it that were funded by the industry. Attached

as Table 11 is a list of publications on nicotine and the pharmacology of tobacco use in addition to these that were or appear to have been funded by the industry. These articles are included in the appendix [B16, N1 - B16, N5; B16, N8; B16, N11; B17, N1; B17, N4; B17, N9 - B17, N11; B17, N23; B18, N7; B19, N4 - B19, N14].

In several cases, the funding source is not directly acknowledged on the paper. However, the American Tobacco Company published a pamphlet in 1962 that listed company-supported extramural research [B9, N12]. Two papers by Wolff from 1948 acknowledge William Esty & Co. as the sponsor. At the time, Esty held the advertising account for Camel (RJR).

While the industry-funded research literature on nicotine pharmacology is large, there seems to be no literature, from within the industry or from elsewhere, relating to the taste and flavor of nicotine. ASAM knows of no articles on the taste or the flavor of nicotine. This is a peculiar state of affairs if the nicotine in tobacco products is actually there for these purposes.

PART B

Comment to

The Food and Drug Administration

Regarding

Docket No. 95N-0253

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents

21 CFR Part 801, et al.

American Society of Addiction Medicine

4601 North Park Avenue
Upper Arcade, Suite 101
Chevy Chase, MD 20815

301-656-3920
fax: 301-656-3815

The preparation of this comment was supported in part by grant number 026766 from the Robert Wood Johnson Foundation

Comments on Proposed 21 CFR 897

General Observations

Nicotine addiction is the most common serious medical problem in the United States. According to the 1994 Household Survey of Drug Abuse, 60 million Americans aged 12 and above, including 4 million aged 12-17, used cigarettes in the past month [B8, N8; B11, N2][1]. This represents 29% of the population. Among those who continue to smoke, half will die because of smoking [B11, N1]. As the agency has detailed in its proposal, most who use tobacco products regularly are addicted to nicotine. Worldwide, the World Health Organization estimates that more than one billion people smoke cigarettes and that three million will die in 1996 alone from the cigarette. This is more than are killed by the world's second leading killer, tuberculosis. Unless effective control measures are put in place, the worldwide death toll will reach 10 million per year in another thirty years.

Nicotine addiction is a complex phenomenon that must be dealt with at many levels to bring the terrible epidemic of tobacco-caused disease under control. As the agency has indicated, solving this enormous public health problem will be possible only if each level of government, federal, state and local, as well as each part of the private sector, and each member of the international community, does what it can to control the tobacco problem. The Food and Drug Administration has a major role to play in fostering tobacco control. That role is not dissimilar from the one the agency has long had in protecting the food supply: Federal regulations provide a reliable basis for consumer confidence both here and abroad in the wholesomeness and accurate labeling of foods produced or sold here, but FDA rules are complemented by state and local efforts such as sanitary inspections. Similarly, the agency envisions its proposed rule as a regulatory floor, not a ceiling, and this is extremely important for public health. In our federal system, the states have the primary responsibility for protecting the health of their citizens, but in some areas, such as the marketing of dangerous consumer goods in interstate commerce, federal regulation has obvious advantages. Nicotine addiction is also an international problem, and the regulatory system put in place in the United States will influence approaches other governments take to deal with this devastating epidemic.

The FDA's proposal and its supporting materials are a thorough, knowledgeable and authoritative analysis and set of regulations. The proposed regulations are carefully framed and are solidly grounded in the data.

Preventing tobacco use and nicotine addiction among the young is an appropriate focus for FDA regulation, and the agency's proposal would go far towards attenuating the

[1] In this submission, appended material is collected into numbered binders and a box. The contents of these are listed at the back of the comments. In the text, appendices are referred to by binder (B#) and by number within each binder (N#).

flood of marketing for cigarettes and smokeless tobacco products that reaches the young. However, there is much that the agency could do to provide better information than is now available for the benefit of all tobacco users, including teenagers, and to foster an environment which would make it easier for people of all ages to stop smoking (which most smokers want to do) without limiting the supply or availability of tobacco products to adults. Moreover, the agency could conceivably regulate nicotine delivery devices themselves in ways that would reduce their toxicity and their addictiveness. Some suggestions along these lines are contained in the discussion below of Additional Regulatory Measures.

The agency's proposal takes an integrated approach to reducing the reach and appeal to the young of sales and marketing for tobacco products that are used by the young. The agency is correct to approach this with a comprehensive package: if major area of sales or marketing that impact the young is left unregulated, there will be a flow of tobacco company resources through the gaps. This was seen most clearly in this country when the broadcast ban on cigarette ads went into effect in 1971: cigarette advertising shifted to billboards, magazines, newspapers, and sponsorships (see the 1993 FTC report on cigarette advertising, cited by the agency). Several cigarette companies (RJ Reynolds and Lorillard) began advertising little cigars on television for the first time in response to the cigarette ad ban [B9, N1; B11, N3].[2] Members of Congress successfully pressed these companies to voluntarily stop these ads, but the refusal of one cigar company to participate in this voluntary agreement made it necessary for Congress to pass the Little Cigar Act of 1972.

Smokeless tobacco makers circumvent the Federal Trade Commission regulation that bars them from using the brand names of smokeless tobacco products on promotional items such as caps and t-shirts. For instance, rather than stop making such items, UST has registered Skoal Bandit Racing, Skoal - Copenhagen Pro Rodeo and Skoal Music as service marks and places these names on many of the items it offers the public thereby evading the Commission's regulation [B11; N4].

Numerous examples are available from other countries of how laws and regulations restricting cigarette advertising are undermined and circumvented by tobacco companies. When France banned cigarette advertising from magazines, Philip Morris set up a travel agency and advertised "Marlboro Country Travel" in French magazines [B1, N32]. Auto and motorcycle racing are major venues for cigarette advertising in Europe. Branded clothing (Marlboro), sports watches (Camel and Marlboro) and boots (Camel) are sold in Europe and elsewhere using the colors and logos of these respective brands [B1, N33-36; B2, N32-34]. In Canada, where sponsorship in the brand name of tobacco products has been banned, the cigarette makers have incorporated the brand names into shell companies that are sponsors of sporting and cultural events. In Malaysia, cigarette companies have set up travel agencies (Marlboro, Kent, Peter Stuyvesant), clothing stores

[2] This was despite the fact that cigarette consumption actually rose following the ad ban [B14, N13]. Counterads that had been mandated by the FCC left the air and marketing resources were redirected into other venues (See the FTC reports on cigarette advertising).

(Camel), jewelry stores (Benson & Hedges), luxury auto dealerships (More), record stores (Salem), and concert and movie promotions (Salem and More) [B5, N54-55] to advertise cigarettes in a country that has banned cigarette advertising. This consistent international experience demonstrates the need for regulations of this sort to be comprehensive and for the agency's proposal to be judged as a whole rather than merely as the sum of its parts.

While ASAM regards the proposal as a sound basis for regulating cigarettes and smokeless tobacco, a number of specific suggestions are detailed below which would close some loopholes that are apparent in the agency's proposal.[3]

The tobacco industry is fundamentally different from other industries that FDA regulates in that it behaves in ways which damage the public health despite knowing of the harm that it is doing. It masks the harm and its knowledge of it with official dogmas, rhetoric and policies that, upon close examination, are just window-dressing [for instance, B11, N6]. As detailed in the agency's proposal and discussed in a recent issue of *JAMA*, the journal of the American Medical Association [B8, N5, pp 225-233], tobacco companies have long known that their products addict. Moreover, the Brown & Williamson documents, which the agency has, indicate that BAT and B&W have long known that tobacco products cause serious disease in some of their best customers.[4] Unlike the relationship the agency enjoys with other regulated industries, in which there is a common interest in protecting the public health, this industry has consistently acted in ways which have recklessly ignored the public health while pretending that it is being responsible. This means that the agency should fashion the proposed regulation in ways which give the regulated companies new, clear, obvious, and compelling incentives to act in a cooperative manner so that they support and do not undermine the regulation. A specific suggestion to accomplish this, requiring each company to report to the FDA each year the number of customers it has who are under 18 years of age, is discussed below.

FDA has proposed a seven year time in which a final rule would be operative. By the end of the seven year period, the agency expects that tobacco use among the young will fall by 50%. If, during that time, this goal is not achieved, the agency would then propose further regulations. ASAM strongly supports the concept behind this aspect of the proposal. The goal of a 50% reduction in teen tobacco use ties the regulation to a specific, measurable, relevant, and achievable objective. It is an achievable objective as demonstrated by the rapid fall in prevalence of cigarette smoking among African American teens during the 1980s, although smoking rates are now rising in this population [B9, N11].

---

[3] The Canadian government recently announced that it would seek a new legislative framework for the control of its tobacco epidemic [B11, N5]. While sharing many characteristics of the FDA proposal, the Canadian proposal takes some additional steps. While the Canadian government has decided to seek new legislation to accomplish a similar task, ASAM believes that the Food, Drug and Cosmetic Act provides a sufficiently robust framework for FDA to accomplish the task outlined in the proposed regulation. The Society therefore sees no need for new legislation to define the role FDA should have in dealing with the tobacco epidemic in the US. The agency has sufficient authority to act under existing law.

[4] The appendix includes a CD ROM version of the Brown & Williamson documents published by the University of California [B5, N56].

However, ASAM recommends that the agency not be bound by the seven year time frame it is imposing on itself in four areas. These are:

First, the agency should start counting the seven year period from the date of final publication of the regulation and not from the final adjudication of any legal proceedings that may delay its implementation. With every year's delay in implementing a final rule, another cohort of young people becomes addicted to nicotine. The agency's goal is to reduce the number of new regular users of tobacco each year among the nation's young by 500,000. Postponing final implementation by a year means that another 500,000 young people will become regular users of tobacco products, and of these, more than 160,000 will eventually die prematurely because of a tobacco-caused disease.

Second, the agency should not feel constrained by the seven year time period to change or add regulations that are necessary to remedy abuses, undermining or circumvention of the regulations by the tobacco companies or their allies.

Third, if, during the seven year period, tobacco problems become worse in particular segments (e.g. an increase in cigarette use among young African Americans or an increase in smokeless tobacco use among young females), or if new tobacco problems arise in this population (e.g. an increase in cigar use among teens of any subgroup), the agency should immediately examine the particular situation and ascertain whether additional regulatory measures are appropriate at that time.

Fourth, the agency should actively seek information relevant to the regulation of the products themselves and relevant to improved sharing of information with consumers in an ongoing fashion. If significant advances in product design or engineering which would protect the public health become apparent to the agency or if significantly important approaches to improved sharing of information about tobacco products with consumers are developed, the agency should not be limited by a seven year rule if that alone becomes a reason for delaying implementation of important protections to the public health such as these.

ASAM agrees with the agency that the available evidence supports a regulation that would completely ban marketing (advertising and promotion) for cigarettes and smokeless tobacco products. ASAM has recently joined the list of distinguished organizations that have called for such a ban.

Finally, some cigarettes and smokeless tobacco products brands manufactured in this country for export. Nicotine addiction is a pediatric disease throughout the world, not only in the United States. The final rule should indicate that the regulations apply to products manufactured for export as well to the extent that there is no conflict with foreign law. There is a precedent for this. In 1989, FDA regulated a brand of cigarette

named Spectra as a drug even though it was not sold in this country but only manufactured here for export.

Subpart A – General Provisions

Sections 897.1 and 897.2, Scope and Purpose

Cigarettes and smokeless tobacco products are nicotine delivery devices and they regularly cause addiction in their users. Because addiction often leads to serious illness and death, it is important to reduce the number of people under 18 years of age who become addicted to nicotine. Similarly, it is important to provide accurate information about the use of these products to users and to potential users.

Section 897.3, Definitions

The definitions of "cigarette" and "smokeless tobacco product" both require the presence of nicotine in the products. The agency should consider whether a tobacco company could market a nicotine-free brand extension of a cigarette or a smokeless tobacco product and advertise this product free of the restrictions imposed by the regulations on the nicotine-containing members of the brand family or whether proposed section 897.34(a) prevents this. The advertising for such a product could have advertising value for the nicotine-containing versions of the nicotine-free product thereby undermining the intent of the regulations. Philip Morris has test marketed denicotined versions of both Merit and Benson & Hedges in the recent past.

The proposed definition of "cigarette" appropriately includes what are called in the trade "little cigars" at 897.3(a) (2) and 897.3(a)(3). At least twice in the past, manufacturers have sought to take advantage of the fact that the little cigar contains some tobacco or tobacco derivative in its wrapper. In 1905, attempts were made to sell little cigars where cigarettes had been banned [B11, N7]. In the early 1970s, RJ Reynolds, Lorillard and at least one cigar manufacturer advertised brands of little cigars on television after cigarette advertising had been banned from broadcast media. Congressional action was required to halt the practice, but not before little cigar consumption rose dramatically [B9, N1; B11, N3].[5] (Little cigar sales increased from 1 billion units in 1971 to 3.9 billion units in 1972. Eighty-six percent of the increase was accounted for by RJR's Winchester brand, the one that had been most heavily promoted on television [B9, N2].) Evidence presented to Congress in the early 1970s established that the smoke from little cigars is frequently inhaled by consumers and that the smoke from these products contains substantial amounts of tar and nicotine. FDA is wise to

[5] Congressman Preyer (D, NC), representing Greensboro, NC, home of Lorillard's cigarette plant, observed during the House debate on the Little Cigar Act, "There is no question that the little cigar is designed to compete with the cigarette." [B11, N8, p 29966]

include little cigars within the definition of a cigarette since otherwise, little cigars could be unfairly marketed in ways that are prohibited for cigarettes.

Packages for little cigars are not required to carry a warning label, and advertisements for these products also carry no warning. The agency is not preempted from requiring warnings on packages of these products or in their advertising.

Tobacco sticks, also called tobacco inserts or tobacco rolls, are tobacco rods wrapped in a tissue-like paper. They are intended to be inserted into preformed cigarette tubes. Although not yet marketed in the United States, these products have been sold in Canada and in Germany because of an advantage in the excise tax structure. In Germany, both Philip Morris (Marlboro) and RJ Reynolds (Camel) have sold versions of tobacco rolls [B4, N6]. While these products would seem to be cigarettes (they are tobacco rods wrapped in paper), the governments in both Canada and in Germany have treated them differently from cigarettes. The agency should check the relevant definitions used by the Canadian and German governments to be certain that the definition of "cigarette" used in a final rule includes tobacco sticks.

If tobacco sticks are not covered by the basic definition of "cigarette", they would not be required to carry a warning label, and advertisements for these products would also not be required to carry a warning.

Cigarette tobacco, also called "roll your own" (RYO), is appropriately included in the definition of "cigarette" at 897.3(b). In both Canada and Germany, cigarette companies have promoted brands of cigarette tobacco when there has been a price advantage to do so. In Germany, both Marlboro and Camel have been sold in RYO versions [B4, N5-6]. There is no reason the manufacturers would not find it attractive to do so here if FDA regulations were to leave the marketing and sale of cigarette tobacco unregulated.

Packages of cigarette tobacco are not required to carry a warning label in this country (both Canada and European Community member countries do require this), and advertisements for these products also carry no warning. Example of ads from *Rolling Stone* and a t-shirt for Drum brand cigarette tobacco (none of which carry warning labels) are included as examples of image-based advertising for this category of product [B4, N1-2; B4, N4]. A direct mail piece for Drum is also included [B4, N3]. If cigarette manufacturers in this country felt that the warnings on packages and advertisements for cigarettes were effective in discouraging consumption of their products, they could put out cigarette tobacco versions of their brands. The agency is not preempted from requiring warnings on these products or in their advertising.

While the data on tobacco use by youth show that the problems are with the use of cigarettes and smokeless tobacco products, epidemiologic studies of adolescent tobacco use have usually not asked about cigar use. Moreover, conventional cigars are presently receiving a substantial amount of favorable publicity despite the fact that cigar use can

produce nicotine addiction and cause diseases such as cancer (see the Surgeon General's Reports for 1988 and 1989). Moreover, promotional techniques employed by cigarette and smokeless tobacco purveyors are being used for cigars [B4, N7-11; B7, N11, pp 23, 47, 75],[6] and cigar use is presented in popular magazines as an "in" thing to do [B11, N9]. Cigar ads are appearing on the radio (WOR in New York City recently carried some).

Cigar use may increase among the young as a result of these and other marketing efforts and because of unintended effects of these regulations (for instance, cigars can remain a self-service item in tens of thousands of pharmacies and convenience stores while cigarettes and smokeless tobacco products will be moved behind the counter).

In two recent preliminary studies, cigar use among adolescents in a chemical dependency program has been found to be surprisingly high.

Over a period of several months in early 1995, all males entering inpatient treatment for chemical dependency at a program in New Jersey problems were asked, "Do you currently smoke cigars?" Among 688 adults, 3.5% answered positively. In contrast, 10.7% of the 121 adolescents questioned reported current cigar use. This three fold difference in rates of cigar use is statistically significant at the 0.0004 level (Written communication from Judith Kempf, Ph.D., July 1995).

Twenty-tree adolescent patients at a treatment program for chemical dependency problems in California, were systematically asked about tobacco use, including cigar use, in somewhat more detail. (These are preliminary results from a larger survey that is underway at this facility.) The mean age was 15.8 years; eighteen were male; fourteen were white. Twenty were current cigarette smokers. Nineteen reported having smoked cigars (16 male, 3 female); males had used about twice as many as females. Fifteen reported using "sweet cigars," and five reported having smoked more than a few of these. Among those who used cigars, sweet cigar use was more common among females (three of three) than among males (twelve of sixteen). Swisher Sweet was the most common cigar brand named, and Garcia Y Vega was second.[7] Seven reported having used little cigars. Inhalation of cigar smoke was reported by most who smoked cigars. In contrast to the high prevalence of cigar use, only five reported moist snuff use, and this was reported as being only "very little" to "some" (Written communication from Cathy McDonald, M.D., December 1995).

These two preliminary reports suggest that cigar use may already be not uncommon among adolescents with chemical dependency problems. This population may provide an early warning about the general adolescent population. These data indicate that the agency should monitor the situation through appropriate epidemiologic studies and consider including conventional cigars and other tobacco products within the

[6] At B7, N11, p 139, there is an ad for a cap and t-shirt for Drum brand cigarette tobacco and an opportunity to sign up for the Drum Newsletter.

[7] A promotion for Garcia Y Vega brand cigars is presented in the appendix [B4, N7-8].

scope of its regulations should additional evidence accumulate which indicates that these products are becoming more than very rare contributors to nicotine addiction among the nation's youth.

Subpart B – Sale and Distribution to Persons Under 18 Years of Age

Section 897.10, General responsibilities of manufacturers, distributors and retailers

One effect of this section is to give manufacturers shared responsibility with retailers for not selling cigarettes and smokeless tobacco products to persons under age 18 years. This is an important advance in the prevention of tobacco product sales to minors since for the first time, manufacturers will have a vested interest in seeing that minors are not sold cigarettes or smokeless tobacco products. Manufacturers will have an incentive to foster better training of retailers and retail store staff in checking IDs and in assuring that cigarettes and smokeless tobacco products are only available behind the counter.

Section 897.12, Additional responsibilities of manufacturers

The major manufacturers employ large numbers of sales representatives who visit retail outlets regularly [B11, N10]. Requiring that these sales reps assure compliance at the retail level with the regulations during the normal course of their rounds is an appropriate use of this resource. This requirement should not be burdensome on the manufacturers since the sales reps make these calls anyway.

Section 897.14, Additional responsibilities of retailers

While there are age of sale requirements in each state already, it is helpful that there also be a federal requirement such as this one. ASAM believes that the age of sale for tobacco products should be 21 as it has been for many years in Pennsylvania. Age 19 is more attractive than 18 since many people attain their 18th birthday before leaving high school.

The provision requiring that each sale of the regulated nicotine delivery devices be a face-to-face transaction, without the use of a vending machine, is the only way the agency can assure that the IDs of customers who might be under aged will be checked.[8]

[8] A superior court decision in a case about cigarette vending machines issued recently in New Jersey is included in the appendices since it addresses several of the issues that may come before the agency in its proposal to ban these machines [B11, N11].

The requirement that cigarettes and smokeless tobacco products be sold in unopened packages will eliminate the retail sale of "loosies" which has long been a way for youngsters just starting out with cigarettes to obtain the occasional smoke.

Section 897.16, Conditions of manufacture, sale, and distribution

Restrictions on product names. The agency's proposal lists three cigarette brand names that are also the names of other products that were in use as cigarette brand names on January 1, 1995, namely Harley-Davidson, Cartier, and Ritz by Yves St. Laurent (60 FR 41324). A cigarette brand name directory published by the Tobacco Merchants Association of the United States (Princeton Junction, NJ) lists numerous other cigarette brand names which are the same as other commercial products or entities. While all of the following brand names were in use on nontobacco products on January 1, 1995, with one exception (Dunhill), it is not known if any of the cigarette brands were on the market.

Beech-Nut
Christian Dior
Dunhill
Four Roses
Hallmark
Johnny Walker
Levi's
Life
Listerine
Pierre Cardin International
Playboy
Time
Seven Eleven
Shop-Rite
Vanity Fair
Vogue
Woolworth
Wrangler

Dunhill is a brand name used for cigarettes as well as leather goods and accessories. The nontobacco products are sold in the US and elsewhere. The brand was on the market January 1, 1995.

As described elsewhere, Camel Trophy watches and Camel boots are sold in Europe, Marlboro Racing Watches are sold in Europe, and Marlboro clothing is sold in Europe, Asia and South America. These lines of branded goods appeared as conventional

advertising venues became restricted. Moreover, since at least 1994, Camel has had a mail order business (The Camel Company catalog) for items directly related to the cigarette brand that are sold for cash, without any redemption of coupons or UPC codes [B2, N30-31]. The catalog represents itself as a cigarette advertisement, bearing the required warnings, but the goods it sells appear to be offered without discount, much as merchandise branded with Walt Disney characters or with Coca Cola symbols are sold under license from Walt Disney or Coca Cola as profitable tie-ins to well known brand names.

An Oklahoma company makes a line of tire care accessories under the Camel brand name. The company uses a logo which bears a striking resemblance to the logo for Camel cigarettes, except this animal faces right, not left [B5, N52].

Besides being a brand of chewing gum and a cigarette brand trademark, Beech-nut is a currently marketed brand of chewing tobacco made by the National Tobacco Company [B8, N13].

The appendix includes a list of trademarks of all smokers' articles registered as listed in a 1994 compendium [B11, N12]. While many of the listed trademarks are for cigarette and smokeless tobacco brands, many are also for other products.

The agency should close this loophole completely if at all possible. The language could be at least improved by limiting eligible brand name tie ins to those relating to products both tobacco and nontobacco that were being sold within the United States on January 1, 1995 and to limit eligible cigarette brands to those with greater distribution than that needed to protect a trademark at that date.

Minimum cigarette package size. The agency is aware of Newport being sold in packs of 10. In addition, Virginia Slims has been available in some areas of California recently in 10s, and American Tobacco recently marketed a brand named Special 10s (regular and menthol) in this country which was also packaged in 10s [B4, N12-14]. In the wake of the acquisition of American Tobacco by Brown & Williamson, this was one of the brands that B&W sold to Lorillard [B11, N13]. Moreover, in France, Philip Morris sells three different packings of Marlboro in 10s and RJR sells Camel in 10s [B4, N15-17].

At 60 FR 41324, the agency indicates that it is unaware of pack sizes greater than 20 being used for cigarettes in this country. While many brands were packed in 25s for a brief period in the late 1980s, the one that is currently marketed is Marlboro, in both regular and lights versions [B4, N18-19]. These packages are significant for bearing images of cowboys on the packs, as will be discussed below. Sometimes, a state's tax law makes it advantageous for cigarettes to be packed with more than 20 cigarettes to the pack. In considering what the optimal unit of sale should be, the agency should consider not only the attractiveness of the pack size to a youngster but also whether a larger pack size might encourage increased consumption of cigarettes. While little has been

published in the open literature on this subject, the cigarette makers are certain to have examined this matter very closely. The agency should seek information from the producers to learn more about pack size and consumption patterns. An alternative to increasing the pack size would be to limit cigarette sales to units of a 200 cigarette (10 pack) carton.

The agency does not specify a minimum package size for smokeless tobacco products. By analogy to cigarettes, the minimum package size should be 20 doses of nicotine (considering each cigarette to represent a single dose even though the dose is administered in about ten discrete inhalations, like a dose of medicine to control asthma taken from a nebulizer). Standard dosing sizes should be available from the industry and perhaps from surveys that have been done of smokeless tobacco users, including both epidemiologic studies and case control studies of oral cancer.

Vending machines. The agency is wise to propose a ban of vending machines for nicotine delivery devices. In a survey of cigarette retail outlets in New Jersey last Summer, the New Jersey Health Officers Association found that minors were successful in making cigarette purchases from supposedly locked vending machines in eleven of fifteen attempts. In some instances, the remote control device to operate the machine was sitting on top of the machine to save store personnel the bother of having to press the switch. In Mahwah, New Jersey, a police officer found that a minor had no trouble purchasing cigarettes from a tavern.

The agency cites an industry source for the figure of 77% of vending machines being in supposedly "adult locations" (60 FR 41325, footnote 48). This figure comes from a self-report mail-in survey conducted by a vending machine industry trade organization. The response rate, representativeness of the respondents, manner used to ascertain machine locations (by census, by guess, by other means), and even the proportions of all vending machine operators and machines represented in the survey are, as far as ASAM knows, unknown. Without additional information about how the 77% figure was derived, the agency should not rely on it in any way.

Self-service displays. ASAM agrees with the agency's analysis that self-service displays encourage shoplifting of tobacco products by young people and that their absence increases the likelihood that a clerk will check the IDs of customers who might be underage. The appendix includes photographs of displays that show how difficult it is for retail store personnel to supervise self-service displays and how these displays are often casually placed near candy or toys [B5, N37-42].

Tobacco companies provide retailers with cigarettes for self-service displays at a discount. This is one way the companies use promotional allowance money from their marketing budgets. The practice has the effect of subsidizing shoplifting since the retail merchant makes a higher profit on self-service cigarette packs than on packs displayed behind the counter.

A recent joint meeting of the FDA's Advisory Committees on Drug Abuse and on OTC products recommended that nicotine gum be made available as an OTC product [B12]. The manufacturer's proposal is that nicotine gum be sold from self-service displays. This is not at all at odds with the agency's proposal to require that cigarettes and smokeless tobacco products only be available behind the counter. There is no evidence that teenagers abuse nicotine gum nor is it considered likely that this will occur. On the other hand, four million 12 to 17 year olds have used cigarettes in the past month and large numbers have used smokeless tobacco products [B8, N8]. Nicotine gum does not deliver nicotine to the bloodstream as rapidly as either cigarettes or smokeless tobacco products do (see the 1988 Surgeon General's Report). The recommendation that nicotine gum be available through self-service while these other nicotine delivery devices only be behind the counter represent appropriate, measured judgments about the attendant risks and benefits of these products to potential customers, including both young people and adults. The same Drug Abuse Advisory Committee has recommended that nicotine nasal spray be classified as a controlled substance if it is approved for marketing as a product to aid in the achievement of abstinence from tobacco [B11, N14]. The agency staff work that led to the agency's posing this question for nicotine nasal spray to the Advisory Committee further demonstrates the appropriate, careful, case by case analysis the agency has used, and continues to use, for nicotine delivery devices.

Mail-order sales. It is appropriate that mail-order sales be prohibited since the seller has obvious difficulties verifying the age of the purchaser in selling where there is no face to face encounter. The agency should be certain that delivery by services other than the US Postal Service such as UPS and Federal Express is included in the definition of mail-order.

At least two companies which operate mail-order businesses sell products that are advertised as being "natural" and as containing no additives. American Spirit (which is also sold in many health food stores) and Nat Shermans Naturals are brands which make these representations [B4, N49-53]. ASAM is aware of two instances in which high school students have interpreted these claims as meaning that these brands are safe and not addicting. The extent to which young people are being misled by these claims is unknown, but both parents who reported these episodes indicated that their children had used these advertising claims to defend their smoking and that the parents had not been able to effectively disagree with the false conclusions their sons had reached about these brands at the time.[9]

[9] Another brand that presents itself as not containing additives (including, pointedly, an absence of reconstituted tobacco) is Pure [B4, N54-56]. Pure, made by Tobacco Alternative, Inc. of Buffalo, NY, has begun to appear in self-service displays of convenience stores in central New Jersey. Its package bears the text, "NO chemicals, flavorings, preservatives or reconstituted tobacco are added. 100% natural tobacco makes PURE superior to all." The new brand Buz (Star Tobacco) also claims to be "natural." The fact that several companies see a marketing opportunity in selling products whose main feature is their lack of additives indicates that consumers are concerned about what is in the tobacco products they consume. At the same time, consumers are held in the dark by the manufacturers about the contents and yields of these products.

The Star Tobacco Company of Petersburg, VA advertises its mail-order business through a web site the Internet at http://www.startobacco.com [B11, N15]. The site offers links to other tobacco-related sites as well. Star Tobacco's web site is cigarette advertising (The page includes the required warning). Since Internet connections are largely carried over telephone lines, which are regulated by the FCC, these advertisements would seem to be prohibited by the federal ban on cigarette advertising through electronic media regulated by the FCC.

Another benefit of banning mail-order sales is that it will help prevent interstate and international tax avoidance since tobacco products sold in one jurisdiction may not pay as high a tax as those sold in another.

At 60 FR 41326, the agency indicates that Philip Morris plans to discontinue mail order sales. ASAM is not aware that Philip Morris has a mail order business for cigarettes. The company has had a program of free sampling for its cigarette brands which it has said it will be stopping voluntarily through its "Action Against Access" program.

Free sampling. A ban on free sampling is needed to protect young people from tobacco products.

UST only free samples its starter brands, Skoal Bandits and the various flavored Long Cuts [B3, N4; B4, N66-69]. It does not sample the "graduation" brand, Copenhagen. The Conwood company also free samples one of its moist snuff brands [B4, N69-70]. (At 60 FR 41326, the agency indicates that free sampling is the smokeless tobacco industry's largest expenditure. This is incorrect: free sampling is the industry's largest *marketing* expenditure.)

Although RJ Reynolds began checking IDs for the sampling it does at auto races as a result of an expose by the television magazine show "A Current Affair" which was broadcast on November 3, 1995 [B11, N16], the company makes no attempt to check IDs when it gives away samples through the mails. In the past year, RJR has had large sampling programs for Camel and for Winston Select involving free packs and cartons given away through the mails [B4, N64-65; B7, N4-5]. Moreover, RJR sent free packs of Camel brand cigarettes to people on its mailing list as a holiday present, "from the Camel family." Photographs of the two specially designed packs used in this mailing are included in the appendix as well as one of the packs and its mailing container [B4, N58-63].[10] These arrived in mid-December, well after the company suddenly found it necessary to check IDs of people who wanted free samples at auto races. RJR made a change in the way it managed free sampling at auto races after it was caught by a television camera, but the company has not changed its practice for its direct mail work

[10] Included with the free pack was a discount coupon that was coded with numbers that would permit RJR to learn who had redeemed the coupon. Compare the numbers along the bottom of the coupon with those on the mailing label [B4, N63]. Both RJR and Philip Morris often mark coupons that are mailed to track usage in this way.

despite the fact that an estimated 1.6 million 12-17 year olds are on tobacco company mailing lists [B13, N1, pp 253-257].

Recently, the Attorney General of Massachusetts sued UST for mailing free samples of smokeless tobacco products to minors [B13, N2]. The state reached a settlement with UST in which the company agreed to send free samples in Massachusetts only to requesting individuals who have provided a photocopy of a photo ID to the company with a driver's license number. While still not as good as checking ID in a face to face encounter, this is a substantial improvement over previous practice. However, UST has not announced that it will voluntarily follow the same practice in any other jurisdiction, and the settlement only applies to UST, not to other companies that have sampling programs.

In announcing its "Action Against Access" (AAA) program last June, Philip Morris U.S.A. indicated that it will stop free sampling of its cigarette brands [B11, N6]. While it is not clear if the company plans to stop free sampling only in this country or in every country in which it does business, the AAA program was only announced in this country, by the domestic tobacco subsidiary, Philip Morris U.S.A. If the company is stopping free sampling only in the United States, the policy has been devised in reaction to the specific public relations pressure it is under here on the youth smoking issue; it has not actually been motivated by an overall desire to keep its products out of the hands of young people.

Perhaps more telling is the fact that Action Against Access, like all tobacco industry voluntary programs, lacks specific performance goals and objectives. That is, unlike the FDA proposal, which specifically seeks to reduce tobacco use among those under age 18 by 50% in seven years, the AAA program has no measurable target by which Philip Morris can measure its success or failure. The absence of a performance standard means that the company can claim to be doing good while actually accomplishing little or nothing. This also stands in contrast to the way Philip Morris runs its business: the company keeps close tabs on the performance of its many products to make strategic decisions about how to manage the sales and marketing efforts needed to best nurture each brand.

Subpart C – Labels and Educational Programs

Section 897.24, Established names for cigarettes and smokeless tobacco products

In addition to the established names set forth in the proposed regulation at section 897.24, the established name for little cigars and tobacco sticks should also be specified as "little cigars" and "tobacco sticks" in keeping with the manner and style of the established names to be used for smokeless tobacco products.

Section 897.29, Educational programs concerning cigarettes and smokeless tobacco products

The agency is wise to seek to implement the recommendations for an educational program found in the 1994 Surgeon General's Report and in the IOM report, *Growing Up Tobacco Free*. The need for a remedial program to undo decades of tobacco product marketing that appeals to the young is apparent: most who are now addicted to nicotine began using tobacco products in childhood and adolescence, and there is evidence that advertising campaigns have long stimulated the uptake of tobacco use [B13, N3]. Moreover, as the agency details in its proposal, educational programs can work.[11]

ASAM is concerned, however, that the specific structure in the proposed rule is insufficient to accomplish the desired result of reducing tobacco use by the young. Neither the scope nor the form of the proposal seem fully adequate to the task.

The agency described the successful program under the FCC's Fairness Doctrine from the late 1960s as an example to be emulated. However, the proposal makes several errors in arriving at the figure of $150 million as the total amount to be spent on this program. First, the agency cuts in half the figure that it calculates would finance a program of presumed equal coverage to the one mounted in the late 1960s. If the effect is to be duplicated, 100% of the amount should be available, not 50%. Second, in arriving at the $150 million figure, the agency does not consider the fact that the rate of increase in marketing expenditures for cigarettes has been much greater than the rate of inflation. The counterads in the late 1960s were broadcast in a ratio of 1:3 compared to cigarette advertising. A 1:3 ratio in 1995, using the most recently available marketing

[11] In 1970, E. C. Hargrove, writing about the recommendations contained in an advance copy of a Royal College of Physician's report on smoking which he was secretly circulating to the heads of BAT affiliates around the globe, observed, "It will be noted that these recommendations do not include one anti-smoking measure which is considered to have been effective in the U. S. A. – namely, frequent professionally produced anti-cigarette smoking spots on TV." [B13, N4]

expenditures for cigarettes (for the year 1993), would be $2 billion.[12] Since the cigarette companies spend about 25 cents per pack for marketing, this would represent about 8 cents per pack of 20 cigarettes. In contrast, the agency's proposal amounts to only 0.6 cent per pack. It is not likely that a program budgeted at $150 million per year would have a measurable benefit. Besides, this amount is less than 15% of what young people spend on tobacco products each year and is only about half the profit that tobacco companies make on sales to minors [B13, N5].

The agency has proposed that the costs of the program will be apportioned among cigarette and smokeless tobacco product manufacturers according to their shares of the market. To provide an additional incentive to insure that these products are not sold to persons under 18 years of age, the agency should instead apportion the share of this program among tobacco companies based on their share of the under 18 year old market. The information on brand-specific, and hence company-specific, market share would be readily available if the agency adopts the suggestion discussed below at section 897.40.

There are some problems with the structure of the program that the agency outlines at 60 FR 41327 - 60 FR 41328. While the overall plan for identifying messages to be used and for specifying the way commercial time is to be purchased are both well conceived, having the remedial marketing campaign be directly sponsored by the tobacco product makers is problematic. It is hard to imagine that an effective campaign would not include fairly blunt messages about addiction, disease and death from tobacco products. It is equally hard to imagine that a tobacco product manufacturer would broadcast such messages under its own corporate name because of the way that association would signal acceptance of these concepts by the company with its attendant threat to the company's fundamental legal positions in various lawsuits. This means that, if the marketing effort were to be the responsibility of the manufacturers, as outlined in the proposal, each message would include a disclaimer of some sort that said, in effect, "We're being made to do this but we don't believe in it."

A possible solution to this problem would be for the tobacco companies to give the money for the educational program to a (truly) independent group. That way, the companies' various legal positions would not be inadvertently compromised and the messages could be put out without compromise.

If the tobacco companies had a genuine incentive to reduce the number of their customers who are under 18 years of age, then perhaps they would themselves find a way to run the envisioned educational program in a conscientious way. A suggestion for such an incentive is described below, at section 897.40.

While ASAM agrees that the bulk of the educational program should be devoted to television advertising, the Society does not think that the remainder should be limited to radio and outdoor, especially if the final funding level is closer to 8 cents per pack

[12] The fact that this seems like a lot of money arises from the fact that the amount being spent to promote cigarettes really *is* a lot of money.

instead of 0.6 cent. Point of sale messages (including messages on items such as clocks, thermometers, and penny cups at the cash register) could be utilized effectively and could at least partially offset possible reductions in promotional allowances that retailers may experience from the elimination of self-service displays. Advertising in magazines identified as having a high youth readership would also be an appropriate way to reach the target audience and would help any magazines that experienced a decline in tobacco advertising revenues because the companies decided to pull back from media in which they were limited to black and white, text only ads. Direct mail could be part of the program as well since an estimated 1.6 million persons under 18 years of age are on tobacco company mailing lists and these lists are expected to include young people who are especially predisposed to tobacco use. In addition, the agency should consider requiring that "Dear Doctor" letters to pediatricians and to family practitioners be sent on a regular basis as part of the program to educate physicians who care for the nation's youth in what they can do to prevent and manage nicotine addiction among the young. Finally, sports sponsorship to discourage youth smoking has been a feature of some public health campaigns in Australia and should be considered here as well.

Subpart D, Labeling and Advertising

ASAM is proud to join the list of distinguished organizations the agency recognizes at 60 FR 41328 as advocating a complete ban on tobacco marketing. The Society agrees with the agency that the data at hand justify a complete ban. Since the agency has decided not to propose a complete ban at this time, however, the comments that follow are directed to the specifics of the far more limited proposal the agency has made.

The tobacco companies can be counted on to test the limits of any regulation short of a complete ban. The discussion that follows outlines some of the foreseeable ways that the companies may try to circumvent the intent of the agency's proposal, which is to reduce the amount of tobacco product marketing that is attractive to the young. The appendix includes examples of recent tobacco company marketing efforts that may not have been available to the agency. Catalogs for promotional items, matchbook cover designs, direct mail pieces, point of sale material, some conventional advertising as well as some promotional items are included in the appendix [See B1; B2; B3; B4; B5; B7].[13]

FDA is wise to have fashioned its proposed regulations on marketing around limits, category by category, on marketing approaches that have a high likelihood of reaching young people. The alternative approach, deciding on a case by case basis which examples of advertising and promotion appeal to young people, would be impossible to successfully carry out. The latter approach would mire the agency in an enormous amount of review and spark constant arguments with the industry. In the end, it would accomplish little. The Joe Camel ad campaign is an instructive case in point. For more than four years, RJ Reynolds has managed to sustain an argument that this campaign, despite its especially flagrant youth appeal, does not, in fact, do what it does.

The Joe Camel situation is reminiscent of the problems the FTC faced from the 1930s through the 1950s when, in attempting to regulate cigarette advertising, it faced continual challenges from the affected companies delaying implementation of its orders. This resulted in the advertising at issue successfully running its course. The cigarette companies continued to benefit from advertising that made flagrant health claims even though the cases might eventually be adjudicated in favor of the Commission [B6, N62; B8, N14, p 84].

---

[13] Among the promotional items included with this submission are a Skoal-branded knife and a Copenhagen-branded knife [B3, N6; B3, N10]. Pocket knives are common offerings from UST, and they have been placed on offer by mail for *cash* (as little as $3) as well as check and money order. Besides having intrinsic interest for young, male moist snuff customers, a knife may be the best tool for opening a can of moist snuff because of the way the can is sealed shut by its glued-on, circumferential paper label. See item B7, N8.

Sections 897.30 and 897.32, Scope of permissible forms of labeling and advertising and Format and content requirements for labeling and advertising

The package label. Section 897.30 exempts the package label from regulation. This is a major omission since the package design itself is an advertisement. Important examples of this are the use that Philip Morris makes of the Marlboro package's red roof design as a motif in promotional items and in the decoration of its race cars and the way that RJ Reynolds uses the "classic" camel as an icon in its advertising. Moreover, some cigarette companies have recently used the package in innovative ways to offer more variety and appeal.

Philip Morris sells a brand named Star in Switzerland which features a dazzling variety of pack designs. The distinguishing feature of the brand is that there are many abstract art pack designs in circulation at any given time. The German brand West (made by Reemtsma) also employs this tactic in its pack designs [B4, N48].

In the United States, Philip Morris uses pictures of a cowboy on packages of Marlboro 25s [B4, N18-19]. This practice turns each pack of 25s into a small magazine ad or billboard poster, directly evoking the fantasy of Marlboro Country.

RJ Reynolds has issued several series of "collectors packs" for Camel and for Winston in recent years. The appendix includes examples from three different series of Camel packs [B4, N20-32; B5, N7; B5, N9]. One featured the cartoon character Joe and the Hard Pack band, another put the classic camel in various vacation venues around the country, and the third depicted Camel advertising from early in the century. A "collector" series on Winston packs depicts race car drivers in the style of the spiderman cartoon character [B4, N33-34; B5, N7-8]. The advertising, point of sale material, and wording on the packs themselves suggest that the packs be collected and saved. Such collecting is more characteristic of someone who is 12 years sold than someone 30 years old.[14]

RJ Reynolds has recently launched a series of brands under the name of a newly created, wholly-owned subsidiary, the Moonlight Tobacco Company [B4, N35-39; B13, N7]. These brands, evoking various New Age (Sedona) and young images (Jumbo) with attractive, art deco designs, seem a throwback to tobacco marketing of the last century. Before mass marketing techniques were developed, cigarette makers sold many different brands and relied on brand name and package design for much of the marketing appeal of their products. With the advent of mass marketing techniques, companies concentrated on fewer brands. Now, it seems, as regulatory pressure constricts the ability of tobacco companies to use mass market channels of communication, RJ Reynolds is experimenting with the marketing power of brand proliferation.

[14] Collecting is common among older children and adolescents. The collecting of Absolut Vodka ads by children was described in an article in The New York Times of December 24 [B13, N6]. This activity has developed without the cue to "collect all ten" that RJR suggests for its most recent collector packs of Camel or the cue to "collect 'em all" for one of its matchbook sets [B1, N30-31; B2, N23-29; B5, N10-13].

Tobacco products have always had evocative brand names and pack designs. Murad, Home Run, Clown, and Wings are some of the brand names in use earlier in the century. New brands are coming onto the market that derive their energy from the name and package. Buz, from the Exotic Tobacco Company in Utah (in partnership with Star Tobacco of Virginia [see *Brandweek* story on Buz at B13, N7]), uses the slogan, "Industrial Strength Flavoring," even though it styles itself as being a natural product [B4, N47]. Rave, a brand available in parts of California, evokes the Rave Party, which features illicit drug use [B4, N46]. The person who uses this brand can participate in a rave without having to be there. Star Tobacco's brands carry themselves on the strength of their pack designs and names [B11, N15]. Dave's, from Dave's Tobacco Company (actually a Philip Morris subsidiary) is the tobacco giant's entry into the rapidly emerging "microsmokes" market [B4, N40-45].

In summary, the package label, featuring the brand name showcased in an engaging design, has always been a powerful advertising medium. Because of pressures on other forms of marketing, the label is now poised to become even more important to tobacco companies. Philip Morris, RJ Reynolds and other companies are actively expanding the advertising power of the package label at a time when regulatory pressure may limit their ability to use image-based advertising in other media. New products have come onto the market from what appear to be start-up companies which rely on a powerful brand name and dynamic packaging. These trends increase the importance of requiring that cigarettes and smokeless tobacco products be packaged only in plain packaging as has been suggested in Canada [B13, N8].[15]

Regulated media. The media listed in section 897.30 provide manufacturers with a wide variety of means for communicating with their customers.[16] Young people are commonly exposed to each of the regulated media, so each medium should remain on the list of regulated venues.

Of special concern is the enormous use the industry has recently made of direct mail. Both Philip Morris and RJ Reynolds maintain data bases with tens of millions of names. Both companies regularly use these lists for mailings which are often elaborately printed materials with contests, coupons, offers, questionnaires, club memberships, and even birthday cards. A few of these mail pieces, as well as some from UST, are included in the appendices [B1, N7; B1, N22-24; B1, N29; B2, N6; B2, N15; B2, N30-31; B3, N6-7; B3, N9; B3, N10-11; B3, N18-19; B4, N3; B4, N44; B4, N49-50; B4, N54; B4, N60-

[15] Dr. S. J. Green, who was the director of research and development at BAT in the 1970s, thought that conventional cigarettes should not be advertised and should only be sold in plain wrappers [B13, N9] In an ideal world, Dr. Green wrote, "Brand names would be limited to low tar cigarettes and all other cigarettes would be sold in plain white packets with no visual connection with low tar brands, and carrying suitable material to help the addicted."

[16] In Europe, it is not uncommon for cigarette makers to advertise their brands through commercials before or at the intermission of movies shown in movie houses. Product placements in movies were common for cigarette brands in the US through most of the 80s. The agency proposal does not permit either form of advertising, since they are not on the list of what is permitted. This is appropriate.

65; B5, N15; B5, N29-35; B7, N4-5]. These examples demonstrate some of the powerful creative work that companies share with their direct mail customers. RJ Reynolds has even distributed videos about several of its cigarette brands (Now and Winston Select) through the mails in recent years.

No tobacco company can be certain that its list does not include people who are younger than 18 years of age. In fact, in a nationwide, random digit dial survey of 12-17 year olds conducted in the summer of 1993, fully 7.6% of respondents indicated that they had received mail addressed personally to them from a tobacco company [B13, N1, pp 253-257]. Projected to the entire population, this finding suggests that 1.6 million persons aged 12-17 years old are on these mailing lists.[17] Clearly, it is important that any regulation of tobacco product advertising include the uniquely powerful medium of direct mail as a regulated category of marketing.

The definition the agency proposes of adult periodicals (those having greater than 85% adult audience and not more than 2 million young audience) is an appropriate operational definition of periodicals that reach the young less than do those which do not have these characteristics. It would be a mistake to base the definition of restricted publications on the subscriber base (rather than the reader base). The reader base provides a more accurate profile of who actually is exposed to the advertising contained in a periodical than the subscriber base.

If image-based advertising is to be permitted at all, it should be restricted to periodicals read by adults so that it has little impact on young people. However, the proof will be in the pudding. This is an element that the agency should require the industry to monitor with surveys of ad recall (correlated with tobacco use and intention to use patterns) among the population under age 18 years to help the agency understand the extent to which image-based messages continue to reach the young.

Outdoor advertising placement. The establishment of advertisement-free zones around playgrounds and around primary and secondary schools is a welcome advance.[18] Although the 1,000 foot rule (measured, it should be specified, from the perimeter of the property), is good, a better rule would exclude outdoor advertising for these products from neighborhoods where children live. This is the approach that the city of Baltimore has taken, and this approach has been found to be legal by a US court of appeals [B13, N11].

---

[17] A mailed sweepstakes offer for *Penthouse* is also included in the appendix [B5, N53]. The addressee only exists as an entry on cigarette manufacturer mailing lists. There was no way for the mailing service to verify the age of the individual named (Susan Walsh of Livingston Avenue in New Brunswick, NJ), since that individual does not exist as a physical person. Thus, one of the cigarette makers must have made its list available to another marketer of products targeted to adults, representing to that mailing service that the list it was selling was limited to adults.

[18] Leo Burnett, the advertising executive who played a key role in the makeover of Marlboro in the 1950s, used billboards specifically to reach children in advertising Kellogg's cereals [B13, N10, p 219].

Tobacco companies presently say that they observe a voluntary exclusion zone of 500 feet. However, several community groups in New Jersey have examined the extent to which there is voluntary compliance with this voluntary code. In neither of the communities where this has been examined has there been 100% compliance. In fact, in one community, violations have continued after the sponsors and the billboard companies have been informed of the violations.

In Perth Amboy, NJ, a teen group from the Perth Amboy Community Partnership for Youth examined the extent and placement of tobacco billboards in Latino neighborhoods at three different times. After the first and second surveys, sponsors of billboards in violation of the voluntary agreement and the billboard companies involved were notified of the violations. In 1992, fourteen of eighteen tobacco billboards were within 500 feet of a church, school or hospital. In 1994, ten of twenty were in violation. In 1995, nine of twelve were in violation.

In Irvington, NJ, the Municipal Drug Alliance conducted a similar survey in 1995. It identified ten billboards advertising tobacco products that were in violation of the voluntary code.

Black and white, text only format. The requirement that much of cigarette and smokeless tobacco advertising be limited to a black and white, text only format would be a major advance. However, the agency is mistaken in asserting that this format removes imagery and emotive content from the advertisement. Words alone can be powerfully evocative, and the proposed rule proposes no limits on typography, layout, or shape of the advertisement.

Several years ago, a campaign for Merit featured a picture of the pack accompanied by a few words. The copy for one ad was, simply, "Yo." One of these ads is included in the Appendix [B5, N43]. A current campaign for Basic uses the slogan, "Tastes good, Costs less." The appendix includes an execution of this concept that demonstrates the way a black and white, text only format can be used to create an unusual effect. Cutout footprints, right and left, lead the customer from the door of a convenience store to a Basic display offering a lighter [B5, N44-48]. One footprint says, "Tastes good"; the other says, "Costs less." It is an eye-catching, amusing advertisement.

The intent of the black and white, text only format would be better expressed in a regulation that also limited the type styles, font sizes and shapes of borders and of letters that could be used. The regulation should also specify that all text must be black and all background white. This is an area in which experience with how the companies comply with the regulation might lead to revisions before the full seven year period has elapsed.

An advantage of the permitted forms of advertising is that they will permit continued communication of objective data about the regulated nicotine delivery devices to customers. However, current advertising for these products is virtually devoid of genuinely useful information such as this. Moreover, there is considerable confusion and

misinformation among consumers about the meaning of the messages that are communicated [B10, pp 186-208; B13, N12]. For instance, some young people are misled into believing that claims of "natural" and "no additives" in certain cigarette brands are promises of safety, as described above. As described under section 897.40, the agency should develop regulations that specify the minimum objective information about cigarettes and about smokeless tobacco products that manufacturers must share with their customers.

Audio and video messages. In the spirit of the black and white, text only requirement for printed advertisements likely to reach the young, the final rule should include provisions requiring that audio materials not include music, sound effects or voice processing such as echo effects and that video material be shot in black and white (without special effects) and that it also be free of music, sound effects and voice processing such as echo effects. The rule as proposed would permit the playing the cassette of the Camel Hard Pack band which was featured on page 7 in Camel Cash Catalog IV [B2, N13] at retail outlets.

Established name and intended use. Little cigars and tobacco sticks should be listed as separate products with their own specific established names, "little cigars" and "tobacco sticks."

The brief statement. See Part C of these comments.

Ingredient disclosure and yield information. Tobacco product advertising is virtually devoid of substantive information that can be easily understood by consumers. The FDA could markedly improve this situation by requiring disclosure to consumers of ingredients and expected yields of relevant substances from these products under a variety of smoking conditions along with straightforward explanations of how various materials in smoke or in smokeless tobacco products posed important risks to the consumer. The present system of reporting tar, nicotine and CO yields is grossly inadequate, as detailed in the proceedings of the December 1994 meeting of the Ad Hoc Committee of the President's Cancer Panel under the auspices of the NCI [B10]. There are no disclosures to consumers at all about the yields of nicotine or of other toxic materials that may be expected from the use of smokeless tobacco products.

ASAM urges the FDA to develop regulations for ingredient and yield disclosures in a timely manner. This could include statements in advertising, labeling, package inserts, material available at point of sale, and material available through consumer calls or letters to manufacturers. This process should not be subject to the seven year trial period for the proposal that is presently under consideration.

In the cases of little cigars, tobacco sticks and cigarette tobacco, there are no federal laws which set limits on the disclosure of ingredients, and the law which limits the disclosure of additives in cigarettes only applies to the tobacco that the cigarettes

contain and not to additives to the paper or to the filter.[19] Moreover, there are no limits in the law which restrict the agency from setting requirements for disclosures of yield.

Section 897.34, Sale and distribution of non-tobacco items and services, contests and games of chance and sponsorship of events

Section (a). Section (a) establishes that manufacturers, distributors and retailers may not use brand names or identifying symbols associated with cigarettes or smokeless tobacco products in association with other products or services. This would be a welcome reform. For instance, it would stop the practice of UST of creating entities such as Skoal Bandit Racing and Skoal Music to promote its brands of moist snuff [B3, N12-17; B11, N4] and stop the selling of Camel-branded items through the Camel Company Catalog [B2, N30-31]. It would prevent the establishment of Marlboro clothing stores and travel agencies [B1, N32-34]. It would stop the branded material appearing in Marlboro, Camel, Skoal and Copenhagen catalogs from being offered [See catalogs in B1, B2 and B3]. It would also stop the practice of offering memberships in clubs organized around specific brands such as the Benson & Hedges Privileges Club, the Camel VIP Club and the Winston Winners Club [B5, N28-36; B13, N14]. (Membership in the Camel VIP Club and in the Winston Winners Club is characterized by elaborate mailings, membership cards and exclusive offers for club members only.)

However, there may be relatively easy ways around this provision. If the rights to a brand name were transferred to an entity that was not a manufacturer, a distributor or a retailer, that separate entity could then license back the use of the brand name to the tobacco company and proceed to market, license, distribute or sell other goods and services using that same brand name. One way to close this loophole would be to require manufacturers to own the trademarks and the rights to all associated symbols for each brand they produce.

Tobacco companies may argue that selling branded goods other than cigarettes or smokeless tobacco in the name of the tobacco product is merely deriving the economic benefit of a well-known mark, as Coca Cola and Walt Disney have done. However, this analysis conveniently ignores the marketing value for the tobacco product that such activity generates. The examples noted demonstrate that tobacco companies use commercial tie-ins such as Marlboro clothing and travel agency services and Camel Boots

[19] The major cigarette manufacturers released a list of additives to cigarette tobacco in the Spring of 1994. This list did not disclose the amounts of additives used nor the additive list used in particular brands or brand styles. The list characterized most of the listed ingredients as being either on FDA's "GRAS" list of approved food additives or as being approved for use in foods by FEMA. These attempted reassurances of safety are misleading because they ignore the fact that additives to cigarette tobacco are burned and that the smoke is inhaled. Both conditions are different from the conditions of use of food additives. GRAS or FEMA designations for food additives are not relevant to the use of these materials in cigarette tobacco [B13, N13].

as surrogate advertising for the tobacco product [B13, N15]. If a company wants to obtain the benefits of a well-known mark by selling other products, it should not also be able to sell tobacco products under that mark. To do both undermines marketing restrictions on tobacco products to the detriment of public health.

Marlboro is known throughout the world for its brand name and its characteristic "red roof" design, the distinctive red top on its packs with the inverted V bordering on a white area. Marlboro racing cars are painted in this distinctive pattern, and this pattern has been used as the logo for the Marlboro Grand Prix [B1, N39]. A current mail order offer from Team Penske Apparel depicts youth and even infant sizes of clothing which bear this unmistakable design [B1, N40-43]. Roger Penske owns the Indy-car racing teams that race under the Marlboro name. He is also a member of the Board of Directors of the Philip Morris Companies. The proposed regulation would stop Philip Morris from licensing its trademarked designs for Marlboro for this sort of advertising on children's clothing.

Section (b). Section (b) would stop the practice of offering gifts, whether branded or not, and chances for prizes in association with the sale of cigarettes and smokeless tobacco products. This is a much needed reform. As detailed in a recent set of articles in *Tobacco Control* [B13, N1], young people participate to a marked extent in tobacco company promotions. Pierce and his colleagues have recently shown in an article in *JNCI* that participation, as a component of exposure to tobacco product marketing, predicts susceptibility to use tobacco products better than smoking by those around the individual [B13, N3].

The appendix includes examples of chances for prizes and catalogs which have been offered to the public in connection with the marketing of Marlboro, Camel, Copenhagen, and Skoal brands of cigarette and smokeless tobacco [Catalogs are generally included in B1, B2, B3 and B5; Sweepstakes and chances for prizes can in particular be found at B1, N15; B1, N20-22; B1, N24; B1, N27-29; B2, N17-18; B3, N4]. These promotions all use attractive imagery and prizes that are intrinsically interesting to adolescents. In Camel Cash Hard Goods Catalog [B2, N22] and in the Marlboro Unlimited catalog [B1, N27], several items are offered which do not bear the name of the cigarette brand. Still, they are embedded in the catalog and become associated with the fantasy world created by the catalog. The measure of participation in tobacco company promotions used in the report of the nationwide telephone survey of 12 to 17 year olds [B13, N1, pp 253-257] was the possession of a catalog, the ownership of any promotional item, or the saving of coupons that could be redeemed for promotional items. Catalog ownership was the most common form of participation in tobacco company promotions.

While it is unlikely that anyone under 18 years of age actually has ever received any of the major prizes on offer from the give-aways, the award of prizes is not the point of these marketing tools. The consumer's participation in the fantasy of the prize in association with the brand being promoted is the reason these things are used. A 12 or 14 year old boy is fascinated by the allure of sports cars and off road vehicles long before he

has a driver's license. (The romantic appeal of such vehicles may actually loom larger than the practicalities of driving them *before* the person is able to drive.) Philip Morris, RJ Reynolds and UST have sponsored give-aways of highly appealing vehicles in connection with the tobacco products they sell which are most popular among young people [B1, N15; B2, N18; B3, N4]. Similarly, the Marlboro Adventure Team, the Marlboro Unlimited train trips, and the Marlboro Best of the West Sweepstakes [for instance, B1, N12; B1, N21; B1, N27] each offer the consumer an escape into the fantasy world of Marlboro cigarettes.[20] Since the fancy catalogs and the glossy offers communicate the image-based fantasy of the brand, and these materials often find their ways into young hands, it is important that the offers of prizes and promotional items on redemption through the catalogs (as well as those items distributed through point of sale) be prohibited.

Section (c). Section (c) addresses another major problem in the marketing of cigarettes and smokeless tobacco: sponsorship. The proscription of brand names from sponsored events is another welcome reform. The following is a partial list of events that have been sponsored in the name of cigarettes and smokeless tobacco products:

Benson & Hedges Blues

Marlboro Grand Prix (Indy car races)
Marlboro Cup (horse race)
Marlboro Country Music (concert)
Marlboro Ski Challenge

Virginia Slims Tennis Tournaments

Camel Challenge GT auto races

More Fashion Shows

Winston Cup (NASCAR stock car racing series)
The Winston (a race in the Winston Cup Series)
The Winston Select (a race in the Winston Cup Series)
Winston West Series (auto races)
Winston Drag Racing

Doral-Ryder Open Golf Tournament

Vantage Open Golf Tournament

Kool Jazz Festival

[20] The "Best of the West Sweepstakes" for Marlboro [B1, N20-22] captured the imagination of adolescent males in a drug treatment program in Oakland, California.

Copenhagen/Skoal Pro Rodeo
Copenhagen/Skoal Pulling Circuit
Skoal Outdoors
Skoal Bandit Monster Truck

In addition, Skoal Music has sponsored a rock music concert called Rock the Rockies (May 1995, Denver) and plans to hold a similar concert in the Smokie Mountains in July 1996 called Rock the Smokies. Although these events are not named for the tobacco products being promoted, offers of free tickets for the concerts include advertising for Skoal and an offer for free samples of Long Cut Skoal varieties [B4, N67-69]. These free ticket offers have been distributed through magazine advertisements and point of sale displays. The symbol of the concert series, a winged guitar, has no necessary associations with Skoal brand moist snuff, but the appearance of the Skoal name in association with the concert makes this association. If UST were to continue sponsoring these concerts using the same symbols as now but without the Skoal name, FDA should regard the concert ads as advertising for the moist snuff product because of the associations built up as the concert series began.

Table 12 lists a number of trademarks that tobacco companies have registered for events marketing and for clothing and other items, including soft drinks named for Marlboro and Virginia Slims [B13, N14]. Several trademarks registered by UST as product-related entertainment services specifically mention the televising of the events as an intended purpose of the activity described under the trademark. At the time these particular trademarks were registered, the advertising of smokeless tobacco products on television was not against the law and the mention of television as a purpose for the trademark confirms that television advertising is an intended result of sports sponsorship.

Sponsorship provides advertising for the brands that participate as sponsors. Included in the appendices is the transcript of an ABC News Day One story broadcast last February that reports on the commercial value of sponsorship [B13, N16]. Similarly, a recent story in Winston Cup Scene (October 19, 1995) describes the advertising value sponsors expect to receive from their sponsoships [B13, N17]. This has been documented as well for tobacco product sponsorships.

In 1969, the Chairman of Philip Morris, Joseph Cullman III, speaking on behalf of all cigarette manufacturers, told Congress that the cigarette companies wanted their commercials off of television in part because television advertising reached children in an unavoidable manner [B13, N18]. After the ban on cigarette ads in electronic media went into effect, Mr. Cullman pledged that Philip Morris would adhere to the "letter and spirit" of the law [B13, N19]. Similarly, as reported in *The New York Times*, industry representatives promised to be cooperative [B13, N20]. What actually happened stands in stark contrast to these concerns and promises.

Cigarette advertising for all major brands blossomed onto billboards which, prior to the ban, had only been used consistently by Kool (Brown & Williamson). Billboards

catalog of NASCAR-Winston Cup racing materials illustrates both the sort of promotional materials used to promote Winston, Camel and Skoal and the variety of other major sponsors of these races [B5, N15]. The abundance of other sponsors indicates that auto racing will not fail if tobacco products are not allowed to be event sponsors and if teams sponsored by tobacco products are restricted to black and white uniform and car designs. Similar fears were expressed when cigarette commercials were banned from electronic media, but they proved groundless.

Sponsors do not make a sport such as auto racing or rodeo popular. Auto racing and rodeo are compelling, popular spectator sports in their own right. Popular sports attract sponsors who want to advertise. The Olympics would remain a premier sporting event without Coca-Cola or Kodak. NASCAR stock car racing is among the most popular spectator sports in the nation. Tobacco product sponsorship is simply not needed for these sports to thrive. The audience is not there because of tobacco: tobacco is there because of the audience.

Some entities associated with auto racing have taken steps to distance themselves from tobacco products. A magazine called *Racing for Kids* air brushes out the names and easily seen insignias of tobacco products.[22] The enclosed photo of trading cards from this magazine feature drivers who have had their uniforms altered so that the words "Copenhagen" and "Kodiak" do not appear across their midsections [B5, N26].

Another possibly interesting situation is that which is developing around Moonlight Tobacco Company. RJ Reynolds has developed a series of brands with an art deco style of pack design and is selling them through a wholly owned subsidiary named Moonlight Tobacco [B4, N35-39; B13, N7]. All advertising for these brands is under the company name. Under section (c), it seems that Reynolds could sponsor events in the name of Moonlight Tobacco if that entity existed on January 1, 1995 unless FDA would recognize the name Moonlight Tobacco as being an "indicia of product identification."

Similarly, Philip Morris has been test marketing a brand called Dave's, which it produces through a boutique company named Dave's Tobacco Company [B4, N40-45]. The proposed rule would seem to prevent Dave's Tobacco Company from sponsoring sporting events in its corporate name since this is also an "indicia of product identification."

A number of existing brand names are also corporate names, such as Rothmans and Sampoerna (a brand of clove cigarette (kretek) imported from Indonesia). Rothmans has been a sponsor of sporting events (as well as a team sponsor) in other countries.

[22] *Racing for Kids* targets an audience of children up to about age 12. (A sample issue is included in the appendix [B5, N27]. Winston and Marlboro names have been airbrushed off of photographs on the cover and on pages 22, 24, 27, 28 and 65.) Above age 12, race fans have numerous racing magazines, including one titled *Winston Cup Scene*. None of these other publications mask photographic or editorial references to tobacco products that come up as part of their coverage of the sport.

Finally, Philip Morris has marketed a number of products under the Philip Morris brand name. A brand called Philip Morris Commander may be on the market now and Philip Morris Super Lights is presently sold abroad. Moreover, the company uses several crests as emblems of it brands: Marlboro and Merit share one which declares, "Veni, Vidi, Vici", while Benson & Hedges and the Philip Morris Companies itself each have crests that look similar to the ones on Marlboro and Merit but which, upon close examination, are somewhat different [B14, N1]. Would the corporate crest be judged close enough to that used for Marlboro that the company would have to choose between the two, or could it continue to use both? The proposed rule would seem to prevent Philip Morris from using corporate name for sponsorship if it also had on the market a cigarette brand that used the corporate name as part of its name (such as Philip Morris Commander) and might prevent the use of a crest for corporate identity which might easily be mistaken for an "indicia of product identification."

The agency should examine the wording used in section (c) in light of the examples mentioned in this section to be certain that these instances do not get around the proposed rule.

Section 897.36, False or misleading labeling and advertising

ASAM agrees with the agency that it would not be possible to provide an exhaustive enumeration of all the ways in which advertising can be false or misleading. The general guidance that the proposed rule provides serves the purpose better than would any attempt at a comprehensive listing.

Under this regulation, advertising for cigarettes and smokeless tobacco products will be considered false or misleading if it "omits important information." This is a reasonable rule, and it should be part of the final rule, but it is one that may be difficult for the manufacturers to comply with absent guidance from FDA. Consumers do not know the ingredients of these products or the functions that these ingredients serve. Consumers do not know the doses of nicotine and other critical materials they ingest with these products. Terms such as "light" and "low tar" have little meaning in view of the tendency of consumers to smoke cigarettes differently depending upon the way nicotine delivery has been engineered [B10; B13, N12]. FDA should consider developing standards for the communication of information about these products from the manufacturers to consumers through advertising and other means of communication such as package inserts, information books at retail outlets, and 800 numbers.

Subpart E – Miscellaneous Requirements

Section 897.40, Records and reports

The records and reports required by the agency in its proposal are essential for monitoring compliance. However, FDA has an opportunity to require a report that would provide manufacturers with a strong incentive not only to comply with the regulations but also, perhaps, to go beyond the regulations to achieve the goal envisioned in the proposal. This suggestion may help meet the agency's concern voiced at 60 FR 41362 that the goal of this proposal may not be met if the industry ignores incentives contained in the regulations.

As long as tobacco use by the more than four million persons under 18 years of age who smoke, dip or chew is lumped together into an anonymous mass of unnamed cigarette and smokeless tobacco brands, individual manufacturers avoid being accountable for the parts of the problem to which their products (and marketing) directly contribute. However, if each manufacturer were required to report to the FDA each year the number of persons under 18 years of age who were the customers of its brands, then each company would have a specific measure with which to gauge its relative progress towards reducing the number of underage customers it had.

The reporting would be a form of adverse effects reporting. While illness and death are adverse effects caused by tobacco products, reducing these outcomes is not the immediate objective of the proposed regulations. Preventing tobacco use by young people, the avoiding onset and development of nicotine addiction in the pediatric age group, is the focus of the proposal.

Just as conventional pharmaceutical companies report adverse reactions to medicines that come to their attention to the FDA, each maker of cigarettes and smokeless tobacco products should report to the FDA the number of persons under 18 years of age who use its brands. The reported number would be publicly available and so would be known by stockholders, employees, and the business press as well as by corporate management and the board of directors. It would become possible to measure the progress each company was making towards reducing its part of the problem by 50% within seven years.

For instance, if at baseline Philip Morris products were the ones usually used by 60% of the four million persons under 18 years of age who smoked at the time the final rule went into effect, then it would start with 2.4 million underage customers. Its corporate goal would be to reduce the number of underage customers to not more than 1.2 million within seven years. Management, directors, shareholders, employees, and the public would all be aware of the size of the problem the company faced and would be

able to monitor the company's progress towards meeting the goal. If it became clear that merely complying with the regulations was going to be insufficient to achieve the goal, then it would be obvious to the company's management and board that additional steps would be needed for it to prove to its shareholders, its employees and the public that it was a responsible marketer of cigarettes.

This reporting requirement would make Philip Morris and the other manufacturers accountable for something they each profess to want: each of these companies says that it does not want persons under 18 years of age as its customers. The proposed regulations are designed to help each company achieve this corporate goal; the suggested reporting requirement will help make them responsible for it as well.

Furthermore, should the number of underage customers that a specific company had show an *increase* from year to year, that fact would prompt an even more urgent examination of what that particular company might do differently to reverse the trend.

This reporting requirement would remedy one of the major defects of all voluntary industry efforts in the public health arena to date: the absence of objective goals and evaluation of results. Whether one considers the various advertising codes (different incarnations of the cigarette code or the smokeless code) or the various efforts to publicize the fact that tobacco products should not be sold to young persons, whether from the Tobacco Institute, Philip Morris, RJR or UST, one consistent characteristic has been the striking absence of any evaluation, or plan for evaluation, by the sponsoring company or trade association. Nor has any company or trade association ever tied these programs to specific, measurable outcomes.

FDA might permit companies to use data from the Monitoring the Future survey (with the addition of brand name information to the data collected) or the agency might establish parameters for independently conducted surveys. Either way, each company would participate in an adverse effects reporting system which would provide it with a strong incentive to reduce the number of underage customers over time. This should have the effect of improving compliance with the regulations and, perhaps, even encouraging companies to voluntarily going beyond the minimal requirements of the regulations to achieve a reductions in the numbers of underage customers.

Section 897.42, Preemption of State and local requirements and requests for advisory opinions

The proposed rule clearly establishes that the agency's intent is to provide a floor, not a ceiling, for state and local efforts to control the epidemic of tobacco-caused disease. This is as it should be.

Section 897.44, Additional regulatory measures

The agency proposal outlines three major goals for tobacco use by youth within seven years of the publication of a final rule: a reduction in cigarette use by 50%, a reduction in smokeless tobacco use among males by 50% and no increase in smokeless tobacco use among females. In addition, the agency should be watchful for the following additional threshold conditions:

- No increase in cigarette use among African American youth
- No increase in the use of cigars by any segment of American youth

The Monitoring the Future survey forms a generally sound basis for measuring the effectiveness of these regulations with three caveats.

- First, since Monitoring the Future only measures tobacco use among young people who are in school, an additional measure is needed to learn about trends in tobacco use among those who are not in school.
- Second, Monitoring the Future presently does not collect data on tobacco product brands in use. As discussed under 897.40, this is a serious omission.
- Third, the survey does not inquire about cigar use. Cigar use among the young should be monitored since these products are receiving an enormous amount of favorable publicity at the present time.

The following are suggested additional measures that the agency should consider in case its initial goals are not met in seven years.

- A ban on all marketing activities for cigarettes and smokeless tobacco products. This measure is justified by the evidence and supported by numerous groups that have considered the matter. If the experience elsewhere with partial bans is any guide, the industry will test the limits of the agency's final rule and find ways to circumvent their intent. A complete ban is the best way to deal with this situation.

- If all marketing is not prohibited, ban direct mail marketing for cigarettes and smokeless tobacco products unless the manufacturers can demonstrate to the satisfaction of FDA that their mailing lists contain no persons under 18 years of age. (The tobacco companies profess to not want mailing list customers under 21 years of age, but they have not taken steps to check on this.)
- Focus at least part of the educational program on preventing tobacco use among the young on the issues surrounding tobacco use and pregnancy. This would recognize the facts that 390,000 women under 18 years of age became

pregnant in 1991 (resulting in 200,000 live births), that the smoking rate among these women was about 14%, and that cigarettes cause an enormous burden of morbidity and mortality among the fetus and newborn [B14, N2; B14, N3]. Moreover, most females of this age expect to have children later in life, and this is important information for them to know as they come to terms with cigarettes. The educational program geared to pregnancy might take its cue from the educational program that the makers of Accutane have developed for that product.

- Dear Doctor letters from tobacco companies to physicians who care for adolescents about how physicians can best prevent and treat nicotine addiction in persons under 18 years of age.
- Including mailings (perhaps quarterly) about the importance of not becoming addicted to nicotine and how to stop if already addicted to persons on mailing lists maintained by manufacturers as part of the required educational program. As noted above, an estimated 1.6 million persons under age 18 are on these lists, and this includes many who are not (yet) smokers. However, the mailing lists contain the names and addresses of young individuals who are more susceptible to tobacco use than most people of the same age. Such mailings would have to be sent to all names on the mailing lists since the manufacturers do not know which names belong to persons under 18 years of age, even though they uniformly say that they only want individuals who are at least 21 years of age.
- Setting the age of sale at 19 instead of 18. This would put the age of sale after high school graduation which should make it more difficult for junior high and high school students to obtain cigarettes or smokeless tobacco products.
- Carton-only sales.
- Plain packaging.

The following suggestions should be considered for implementation now, whether or not the present proposals lead to a 50% reduction in nicotine addiction by persons under 18 years of age.

- Make use of 800 numbers to provide consumers with detailed information about ingredients, yields, warnings, side effects, precautions about use and contraindications.
- Provide detailed product information in a book at each retail outlet. Such a book might include complete listings of the following information for each packing of each brand:
    - ingredients in the tobacco, the paper (if any), and the filter (if any).
    - the function(s) of each ingredient.
    - delivered doses of various materials, including nicotine, CO, nitrosamines, acetaldehyde, and other toxins (presented as a

range of possible delivered doses depending on how the cigarette is smoked).

- whether ventilation is used and the extent to which smoke is diluted with room air at various intensities of smoking.
- the proportions of different forms of tobacco leaf, stems, reconstituted tobacco and other laminar elements in the tobacco rod.
- the expected risks to the consumer from continued use of the product over an extended period of, say, 20 years, at the rate, say, of a package per day.

The information in the book might also be available on request by calling an 800 number on each package.

- Provide a package insert detailing information about ingredients, yields, warnings, precautions, contraindications, side effects, and how to get help stopping.
- Require that cigarettes be designed so that they are unlikely to cause fires which injure and kill. A coroner's jury in Ontario recently decided that a cigarette was the cause of a fatal fire and has recommended that the government require that cigarettes be fire-safe [B14, N4].
- Regulate the design and content of cigarettes and smokeless tobacco products. This important area should be approached with caution and deliberation. RJ Reynolds has already consumer-tested at least two products, Premier and Eclipse, that likely offer certain risk reductions compared to cigarettes for people who otherwise cannot stop using nicotine [B8, N6; B14, N5], so the issues involved may arise sooner rather than later. It would be wrong to rush products such as these to market without sorting through all the ways the marketing of such products would impact on all populations likely to be affected, both now and in the future [B14, N6] and without considering what, if anything should be done about the availability of conventional tobacco products.
- Nicotine content reduction to nonaddicting levels for nicotine delivery devices available over the counter [B14, N7]

Technical Notes on Discussion of Proposed Regulations

This section is a set of technical comments that amplifies and clarifies material presented by the agency in the body of its discussion of the proposed regulations. The items are presented in the order in which they appear in the *Federal Register* notice.

60 FR 41329, column c, lower half. The text refers to a study of women and advertising without citing it. The article is by John Pierce and his colleagues at the University of California at San Diego published in *JAMA* in 1994. It is included in the appendix [B13, N3].

60 FR 41330, column a. Imperial Tobacco, Ltd. is an affiliate of Brown & Williamson and both function as subsidiaries of BAT. Imperial Tobacco's brands of cigarettes are sold in the United States [B9, N8].

60 FR 41330, column b. Additional material is provided that supplements reference 119 about the study that Philip Morris carried out in Iowa in the early 1970s [B14, N8].

60 FR 41331, column b, top. When UST sends out free samples of moist snuff products, it also frequently sends a catalog for promotional items which can only be obtained by the redemption of proofs of purchase.

60 FR 41331, column b, middle. Although the tobacco industry likes to refer to the cigarette market as "mature", the market is actually very dynamic. That is, there is lots of movement at the margins with new customers entering the market and many, many current customers trying to leave. Among the latter group, some succeed each year. Furthermore, many former customers relapse at irregular intervals after achieving abstinence of varying lengths of time. "Mature" does not mean static. At best, it means that the total number of customers shows little variation even though there is a lot of movement at the margins. An obvious example of this phenomenon is that most people who presently smoke cigarettes had not had their fist smoke by January 11, 1964 when the Surgeon General's Advisory Committee issued its report on smoking and health.

60 FR 41336, column b. UST uses catalogs in the same manner as RJ Reynolds and Philip Morris to promote its moist snuff brands of smokeless tobacco [See catalog offers and catalogs in B3].

60 FR 41348, column a. The alkaline treatment of snuff is also described in a series of articles that were published in *Tobacco Control*. These are included in the appendix [B9, N9].

60 FR 41349, column c. ASAM agrees with the agency that it is not possible to completely control the supply of tobacco products. However, since tobacco use by young

people is influenced by tobacco use by adults, clinical and public health measures to reduce tobacco use by adults will help reduce tobacco use and nicotine addiction among the young. In other words, nicotine addiction is a communicable disease. Incidence can be reduced by reducing prevalence.

The agency indicates in footnote 6 at this point in the text that it could explore regulations to make cigarettes and smokeless tobacco products less hazardous but that it lacks the data on which to proceed in this direction. ASAM recognizes that this is an area that has been fruitlessly explored for decades, but it remains an area about which the agency should maintain an open mind. Specifically, the agency should set up a process for exploring alternative designs including an investigation into the work that has been accomplished by the tobacco companies themselves but never fully commercialized.

The agency should do this in the context of fashioning a genuinely public health response to the product modification problem [B14, N6]. In the past, product modification has only been considered in the context of those who are already addicted to nicotine and who are unable or unwilling to stop. A public health approach would also include in the analysis any impacts that alternative designs would have on those who would otherwise stop and those who are at risk of starting.

60 FR 41359, column c. The agency expects its program to prevent more than 60,000 early deaths. The proposal does not make clear that this is only the average number of early deaths avoided per year over the first seven years of the program if the program goal of a 50% reduction in youth tobacco use is achieved gradually over that time. The total number of deaths prevented by this program over seven years will be 420,000. By hear seven, there will be 120,000 early deaths avoided per year, and this benefit will continue for each succeeding year that tobacco use among youth does not rise.

60 FR 41361, column a and elsewhere. The term "smoking-related" is used in a context in which "smoking-caused" is correct. A smoking-related illness is one that has the cigarette as one of its several causes. Thus, lung cancer, coronary artery disease, stroke, emphysema, and bladder cancer are all smoking-related illnesses. However, the fraction of these illnesses that is *caused* by the cigarette is not merely smoking-related: it is smoking-caused. In the context at hand, deaths directly attributable to the cigarette are under discussion, so the correct term is "smoking -caused" and not "smoking -related."

A further refinement of terminology is to describe these deaths as being "cigarette-caused" rather than "smoking-caused." The cigarette is the etiologic agent of the illness producing death, not the act of smoking. The act of smoking is merely the process by which the disease-producing toxins are ingested. A death from tuberculosis is not described as a death from the inhalation of tubercle bacilli. A food poisoning is not described as an eating poisoning. For these reasons, "cigarette-caused" is preferred to "smoking-caused."

60 FR 41363, column c, bottom. The phrase, "thousands of tobacco-induced illnesses and fatalities should be "hundreds of thousands of tobacco-induced illnesses and fatalities."

60 FR 41369, column c. The estimate of $2,600 as the average payment to retailers is high since the $1.6 billion in promotional allowances is distributed to wholesalers as well as to retailers. Retailers will not necessarily lose slotting fees if self-service displays are barred. In at least some areas, cigarette companies have continued payments to retailers for favored display space. For instance, Philip Morris has provided clear, plastic cases for the display of cigarette packs and cartons in some stores. These cases are placed on a checkout counter but only accessed from the clerk's side. This arrangement permits prominent display of cigarette packs to customers who are thereby offered cigarettes at close range while being unable to pick up packs or cartons themselves.

The agency reports the conclusion of an industry-supported study by Price Waterhouse that the tobacco industry exerts positive benefits on the economy. However, the paper by Peter Gray that the agency cites as offering a view that is skeptical of this analysis was also supported by the tobacco industry [B14, N9]. Moreover, a Chase Econometrics study, also commissioned by the Tobacco Institute, pointed out that in the absence of the tobacco industry, the economy would be neither better off nor worse off [B14, N10, pp 50-51], but that the specific conditions set up for the analysis (presumably the ones dictated by the client, the Tobacco Institute) made this outcome impossible.

Warner and Fulton have discussed this matter more fully in a recent article [B14, N11].

The World Bank has examined whether there is a net economic benefit to tobacco projects in the developing world. The Bank has concluded that a tobacco industry always represents a net drain on a national economy. This is the basis of the Bank's policy of not funding projects which help build up a nation's tobacco industry [B14, N12].

60 FR 41371. The agency indicates that it has not had complete information about the costs of package inserts. In the past few years, inserts, either contained inside the outer wrapper or stuck to the outer wrapper, have become fairly common on cigarette packs. Every pack of filtered Camel cigarettes has had an insert for the past few years in the form of a Camel Cash coupon. Package inserts are often used by several manufacturers to provide promotional offers and for mailing list building. The cost data needed by the agency for this analysis, then, should be readily available.

PART C

Comment to

The Food and Drug Administration

Regarding

Docket No. 95N-0253

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents

Findings of focus group testing of brief statements reported to the Federal Register of December 1, 1995

American Society of Addiction Medicine

4601 North Park Avenue
Upper Arcade, Suite 101
Chevy Chase, MD 20815

301-656-3920
fax: 301-656-3815

The preparation of this comment was supported in part by grant number 026766 from the Robert Wood Johnson Foundation.

PART C

Comment to

The Food and Drug Administration

Regarding

Docket No. 95N-0253

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents

Findings of focus group testing of brief statements reported to the Federal Register of December 1, 1995

American Society of Addiction Medicine

4601 North Park Avenue
Upper Arcade, Suite 101
Chevy Chase, MD 20815

301-656-3920
fax: 301-656-3815

The preparation of this comment was supported in part by grant number 026766 from the Robert Wood Johnson Foundation.

Comments on Section 897.32 as it relates to the Brief Statement

ASAM strongly supports the required inclusion of brief statements with relevant warnings, precautions, side effects and contraindications in advertising for nicotine-containing cigarettes and smokeless tobacco products.

The observations reported by the agency in the Federal Register of December 1, 1995 from the focus group testing that was done on the brief statements are congruent with what is known about tobacco use among teens and should provide the agency with a sound basis on which to develop the brief statements.

In addition to the statements tested by the agency, listed below are some suggested messages that the agency might consider. These have been written with the focus group results in mind, making the facts specific and detailed, but keeping the messages short.

As the agency has described, an eye-catching border, possibly with an additional graphic element, should be included in the overall design. The statements should not be limited to black type on a white background. Instead, the agency should specify that some of the time the statement be white on black and some of the time black on white. It may also be graphically appealing to use both styles on different lines, or with different words, of the same statement. The agency should specify a minimum size for the statement (expressed as a specific area of the overall advertisement) as well as the type style and font size to be used. The agency should require a black or a white border around the statement of a given thickness and opposite in color to the background of the statement itself. A graphic element, perhaps one specifically fashioned for each different statement, should be developed for use with the statements. Each of these suggestions is intended to increase the likelihood that the statement will be noticed by the young consumer.

In the suggestions listed below, the nicotine delivery device is named as the cause of the problem considered in the statement insofar as possible since it is the product, not the activity, that is the actual cause of the resulting problem. Where an asterisk (*) appears in the following suggestions, the established name of the product being advertised is to be inserted. Where yy appears, the number of times the specific adverse event happens in a year (as estimated by the Office on Smoking and Health) is to be inserted.

The following suggestions are offered for cigarette advertising:

- Cigarettes cause yy deaths from stroke each year.
- Cigarettes cause yy deaths from lung cancer each year.
- Smoking even a few * often leads to nicotine addiction.
- Cigarette smoke causes yy miscarriages each year.
- * wrinkle skin and yellow teeth.

- If you want to stop smoking but can't, ask for help.
- Cigarettes cause yy deaths from sudden infant death syndrome each year.
- * smoke can cause lung cancer in nonsmokers.
- Your smoking makes it more likely that those around you will smoke.
- Cigarettes cause fatal household fires.
- * interfere with peak athletic performance.

The following suggestions are offered for smokeless tobacco advertising:

- Using * even occasionally may lead to nicotine addiction.
- Smokeless tobacco causes yy cases of mouth cancer each year.
- * causes tooth loss.
- * causes gum disease.
- Mouth cancer can be disfiguring.
- YY people die each year from mouth cancer caused by smokeless tobacco.
- If you want to stop (chewing) (dipping) but can't, ask for help.
- Your (chewing) (dipping) makes it more likely that those around you will (chew) (dip).

In summary, ASAM supports the inclusion of brief statements in advertising for cigarettes and smokeless tobacco products and agrees with the agency that the messages should be readily observed by and important to the target audience.

Comments on Section 897.32 as it relates to the Brief Statement

ASAM strongly supports the required inclusion of brief statements with relevant warnings, precautions, side effects and contraindications in advertising for nicotine-containing cigarettes and smokeless tobacco products.

The observations reported by the agency in the Federal Register of December 1, 1995 from the focus group testing that was done on the brief statements are congruent with what is known about tobacco use among teens and should provide the agency with a sound basis on which to develop the brief statements.

In addition to the statements tested by the agency, listed below are some suggested messages that the agency might consider. These have been written with the focus group results in mind, making the facts specific and detailed, but keeping the messages short.

As the agency has described, an eye-catching border, possibly with an additional graphic element, should be included in the overall design. The statements should not be limited to black type on a white background. Instead, the agency should specify that some of the time the statement be white on black and some of the time black on white. It may also be graphically appealing to use both styles on different lines, or with different words, of the same statement. The agency should specify a minimum size for the statement (expressed as a specific area of the overall advertisement) as well as the type style and font size to be used. The agency should require a black or a white border around the statement of a given thickness and opposite in color to the background of the statement itself. A graphic element, perhaps one specifically fashioned for each different statement, should be developed for use with the statements. Each of these suggestions is intended to increase the likelihood that the statement will be noticed by the young consumer.

In the suggestions listed below, the nicotine delivery device is named as the cause of the problem considered in the statement insofar as possible since it is the product, not the activity, that is the actual cause of the resulting problem. Where an asterisk (*) appears in the following suggestions, the established name of the product being advertised is to be inserted. Where yy appears, the number of times the specific adverse event happens in a year (as estimated by the Office on Smoking and Health) is to be inserted.

The following suggestions are offered for cigarette advertising:

- Cigarettes cause yy deaths from stroke each year.
- Cigarettes cause yy deaths from lung cancer each year.
- Smoking even a few * often leads to nicotine addiction.
- Cigarette smoke causes yy miscarriages each year.
- * wrinkle skin and yellow teeth.

- If you want to stop smoking but can't, ask for help.
- Cigarettes cause yy deaths from sudden infant death syndrome each year.
- * smoke can cause lung cancer in nonsmokers.
- Your smoking makes it more likely that those around you will smoke.
- Cigarettes cause fatal household fires.
- * interfere with peak athletic performance.

The following suggestions are offered for smokeless tobacco advertising:

- Using * even occasionally may lead to nicotine addiction.
- Smokeless tobacco causes yy cases of mouth cancer each year.
- * causes tooth loss.
- * causes gum disease.
- Mouth cancer can be disfiguring.
- YY people die each year from mouth cancer caused by smokeless tobacco.
- If you want to stop (chewing) (dipping) but can't, ask for help.
- Your (chewing) (dipping) makes it more likely that those around you will (chew) (dip).

In summary, ASAM supports the inclusion of brief statements in advertising for cigarettes and smokeless tobacco products and agrees with the agency that the messages should be readily observed by and important to the target audience.

2048297341

Table 1

Satisfaction in UST Trademarks

[Trademark name (registration date; registration number)]
[First use = First use in commerce]

Copenhagen It Satisfies (6/19/84; 1,282,751)
Smokeless tobacco, namely, snuff. First use: 1939.

It Satisfies! (10/8/85; 1,364,829)
Smokeless tobacco. First use: 1939.

CW Copenhagen It Satisfies (12/13/88; 1,516,594)
Clothing, namely t-shirts, vests, sweatshirts, sweatpants, sweaters, jackets, shirts and caps. First use: 1/4/88.

CW Copenhagen It Satisfies (5/29/90; 1,598,879)
Smokeless tobacco. First use: 1/4/88.

Satisfaction (2/16/93; 1,753,376)
Cigars. First use: 9/89.

Source: CD-ROM of US Trademarks, US Patent and Trademark Office, August 1995.

2048297342

Table 2 1 of 5

References to public statements

in writings from witihin, or sponsored by, the tobacco industry

BINDER # ITEM #	PAGE	YEAR	AUTHOR (S)	COMPANY AFFILIATION	QUOTE	COMMENT
B 15, N 1	545	1994	Campbell, William I.	Philip Morris U.S.A.	"Cigarette smoking is not addictive. During the March 25th hearing, Commissioner Kessler and members of the subcommittee contended that nicotine is an addictive drug, and, therefore, smokers are drug addicts. I strenuously object to that conclusion."	
B 15, N 1	545	1994	Campbell, William I.	Philip Morris U.S.A.	"Cigarettes contain nicotine because it occurs naturally in tobacco. Nicotine contributes to the taste of cigarettes and the pleasures of smoking.. The presence of nicotine, however, does not make cigarettes a drug or smoking an addiction."	
B 15, N 1	547	1994	Campbell, William I.	Philip Morris U.S.A.	"...Philip Morris does not 'manipulate' or independently 'control' the level of nicotine in our products.	Prepared testimony of William I. Campbell. 04-14-1994
B 15, N 1	547	1994	Campbell, William I.	Philip Morris U.S.A.	"...cigarette smoking is not addictive."	
B 15, N 1	552	1994	Campbell, William I.	Philip Morris U.S.A.	"So, how do we 'manipulate' or independently 'control' nicotine as our critics charge? The answer is we don't. We accept the nicotine levels that result from this process."	The process is based on "creating a cigarette for a tar category" (i.e. "amount of expanded tobacco used; filtration efficiency; and ventilation.")
B 15, N 1	552	1994	Campbell, William I.	Philip Morris U.S.A.	"When creating a cigarette for a tar category, we select a particular tobacco blend and flavors to provide 'uniqueness' for the product."	
B 15, N 1	554	1994	Campbell, William I.	Philip Morris U.S.A.	"Cigarettes contain nicotine because it occurs naturally in tobacco. Nicotine contributes to the taste of cigarettes and the pleasure of smoking. The presence of nicotine, however, does not make cigarettes a drug or smoking and addiction."	
B 15, N 1	559	1994	Johnston, James W.	RJ Reynolds Tobacco Company	"Nicotine plays an essential role in the overall smoking experience. It enhances the taste of the smoke and the way it feels on the smoker's palate, and it contributes to the overall smoking enjoyment."	
B 15, N 1	597	1994	Horrigan, Edward A.	Liggett Group	"In conclusion, let me say that nicotine is a naturally occurring substance in tobacco, which is obviously an intrinsic characteristic of our product."	

2048297343

Table 2 275

References to public statements in writings from witihin, or sponsored by, the tobacco industry

BINDER # ITEM #	PAGE	YEAR	AUTHOR (S)	COMPANY AFFILIATION	QUOTE	COMMENT
B 15, N 1	600	1994	Taddeo, Joseph	U. S. Tobacco Company	"A number of factors interacting with each other affect the taste the ultimate taste, including leaf blend, cut of tobacco, moisture, pH, flavors, and undoubtedly nicotine in the tobacco leaf."	
B 15, N 1	606	1994	UST statement	U. S. Tobacco Company	"The assertion that smokeless tobacco use can be addictive is without merit...While the use of smokeless tobacco may become a settled practice or habit, it is not addictive."	
B 15, N 1	628	1994	Campbell, William I.	Philip Morris U.S.A.	"I believe that nicotine is not addictive, yes."	Response to Mr. Wyden's question as to whether they believed tobacco was addictive or not.
B 15, N 1	628	1994	Horrigan, Edward A.	Liggett Group	"I believe that nicotine is not addictive."	Response to Mr. Wyden's question as to whether they believed tobacco was addictive or not.
B 15, N 1	628	1994	Johnston, Donald	American Tobacco Company	"And I, too, believe that nicotine is not addictive."	Response to Mr. Wyden's question as to whether they believed tobacco was addictive or not.
B 15, N 1	628	1994	Johnston, James W.	RJ Reynolds Tobacco Company	"Mr. Congressman, cigarettes and nicotine clearly do not meet the classic definition of addiction. There is not intoxication."	Response to Mr. Wyden's question as to whether they believed tobacco was addictive or not.
B 15, N 1	628	1994	Taddeo, Joseph	U. S. Tobacco Company	"I don't believe that nicotine or our products are addictive."	Response to Mr. Wyden's question as to whether they believed tobacco was addictive or not.
B 15, N 1	628	1994	Tisch, Andrew H.	Lorillard Tobacco Company	"I believe that nicotine is not addictive."	Response to Mr. Wyden's question as to whether they believed tobacco was addictive or not.
B 15, N 1	695	1994	Johnston, James W.	RJ Reynolds Tobacco Company	"It has a mild pharmacological effect. Those products are marketed as a drug."	Response to questioning concerning nicotine in a nicotine delivery system such as a nicotine patch.
B 15, N 1	695	1994	Johnston, James W.	RJ Reynolds Tobacco Company	"Nicotine provides pleasure. It provides enjoyment."	Nicotines role in people's inability to stop smoking.
B 15, N 1	715	1994	Spears, Alexander W.	Lorillard Tobacco Company	"Higher nicotine levels can be achieved by decreasing oriental and the stem and tobacco sheet and increasing the burley and upper stalk positions of both the flue-cured and the burley tobacco."	Quoted by Mr. Waxman. Paper presented at the 35th Tobacco Chemist Conference
B 15, N 1	718	1994	Campbell, William I.	Philip Morris U.S.A.	"yes"	Yes answer to Mr. Waxman's question to whether or not the company can adjust nicotine levels through blending.

Table 2

References to public statements

In writings from witihin, or sponsored by, the tobacco industry

BINDER # ITEM #	PAGE	YEAR	AUTHOR (S)	COMPANY AFFILIATION	QUOTE	COMMENT
B 15, N 1	718	1994	Horrigan, Edward A.	Liggett Group	"yes"	
B 15, N 1	718	1994	Johnston, James W.	RJ Reynolds Tobacco Company	"yes"	
B 15, N 1	718	1994	Sandefur, Thomas E., Jr.	Brown & Williamson Tobacco Corp.	"yes"	
B 15, N 1	718	1994	Spears, Alexander W.	Lorillard Tobacco Company	"yes"	
B 15, N 1	718	1994	Taddeo, Joseph	U. S. Tobacco Company	"yes"	
B 15, N 1	718	1994	Johnston, James W.	RJ Reynolds Tobacco Company	"...we do not design our cigarettes with any nicotine levels in specifications. We design our cigarettes, this is very important, for tar levels, usually within a band."	
B 15, N 1	751	1994	Johnston, James W.	RJ Reynolds Tobacco Company	"...the fact that when you stop using the product, if you choose to do that, you may experience some symptoms of withdrawal, almost precisely the same ones from caffeine as from nicotine."	Similarities of nicotine and caffeine.
B 15, N 1	752	1994	Spears, Alexander W.	Lorillard Tobacco Company	"The level of nicotine in the tobacco of our products is solely determined by the tobacco that we buy and blending of the different tobaccos during manufacturing."	Statement of 03-25-1994 as quoted by Mr. McMillan.
B 15, N 1	762	1994	Campbell, William I.	Philip Morris U.S.A.	"That tobacco is there for taste and flavor. We need the taste and flavor."	Referring to leaf tobacco, wich has a higher nicotine content than reconstituted tobacco.
B 15, N 1	762	1994	Riehl, Tilford F.	Brown and Williamson Tobacco	"No, sir. We blend for taste, not nicotine."	Answer to the question posed by Mr. Bryant as to whether B & W mixes tobacco for Barclay cigarettes so that it will have a high concentration of nicotine.
B 15, N 1	821	1994	Ellis, Kathy	Philip Morris U.S.A.	"We were trying to look at the CNS effects of some of the analogues, yes."	Response to question (Mr. Waxman) on nicotine analogue research.
B 15, N 2	144	1994	Sandefur, Thomas E.	Brown and Williamson Tobacco	"Mr. Chairman, we strongly believe that nicotine is a very important constituent for taste."	
B 15, N 2	199	1994	Sandefur, Thomas E.	Brown & Williamson Tobacco Corp.	"...very high levels of nicotine content in a delivery in a cigarette would be very, very harsh and irritating...that is not what the consumer prefers...they prefer the just the opposite. They want a mild and satisfying cigarette."	Answer to a question by Mr. McMillan concerning the risk of significantly elevating nicotine levels in accepted brands of cigarettes.
B 15, N 2	200	1994	Sandefur, Thomas E.	Brown and Williamson Tobacco	"Nicotine, in terms of taste as a constituent of taste, is important..."	

2048297345

Table 2

References to public statements

in writings from witihin, or sponsored by, the tobacco industry

BINDER # ITEM #	PAGE	YEAR	AUTHOR (S)	COMPANY AFFILIATION	QUOTE	COMMENT
B 15, N 2	217	1994	Sandefur, Thomas E.	Brown and Williamson Tobacco	"The nicotine is a very important-as I understand it, is a very important constituent of taste. The lowering of nicotine or the raising of nicotine could have to be tested to determine if in fact the blend is acceptable to the smoker."	
B 15, N 2	227	1994	Sandefur, Thomas E.	Brown and Williamson Tobacco	"What we were trying to do was maintain a certain amount of nicotine which gives us better taste-"	
B 15, N 2	247	1994	Johnston, James W.	RJ Reynolds Tobacco Company	"This letter is intended to clarify one simple fact that R.J. Reynolds Tobacco Company does not increase the nicotine in its cigarettes above what it found naturally in tobacco."	Letter to Dr. Kessler dated 02-28-1994
B 15, N 2	247	1994	Johnston, James W.	RJ Reynolds Tobacco Company	"In fact, our processes reduce the amount of nicotine in cigarettes when compared unprocessed tobacco."	Letter to Dr. Kessler dated 02-28-1994
B 15, N 2	253	1994	Sandefur, Thomas E.	Brown and Williamson Tobacco	"I think our company's view is, yes, it is relaxing."	Response to question (Mr. Waxman): "What is your company's views on whether smoking is relaxing?"
B 15, N 2	253	1994	Sandefur, Thomas E.	Brown and Williamson Tobacco	"Yes, I think my company would take that view."	Response to question (Mr. Waxman): "How about useful in relieving stress."
B 15, N 3	171	1994	U.S. Tobacco Company	U.S. Tobacco Company	"...other analytical measurements are taken from time to time, including moisture, grain size, pesticide residue, pH, organic acids, and nicotine at various stages..."	Response to letter from Henry A. Waxman (05-19-1994).
B 15, N 3	172	1994	U.S. Tobacco Company	U.S. Tobacco Company	"Differences in nicotine levels in USTC's smokeless tobacco products result primarily from the tobacco leaf blend."	
B 15, N 3	174	1994	U.S. Tobacco Company	U.S. Tobacco Company	"This statement was not intended to suggest that different blends of tobacco do not result in different nicotine levels."	"U.S. Tobacco does not in any way manipulate or 'spike' the nicotine levels in its tobacco products. Nor does U.S. Tobacco take any action to control the nicotine content of its tobacco products before, during or after the manufacturing process."
B 15, N 3	197	1994	U.S. Tobacco Company	U.S. Tobacco Company	"Consumers define 'satisfaction' according to their own subjective perspectives, regardless of the product involved. The packaging and advertising for many consumer goods and services speak in terms of 'satisfaction' or 'satisfaction guaranteed'."	

Table 2

References to public statements in writings from witihin, or sponsored by, the tobacco industry

BINDER # ITEM #	PAGE	YEAR	AUTHOR (S)	COMPANY AFFILIATION	QUOTE	COMMENT
B 15, N 4	33-34	1994	Philip Morris USA and the American Tobacco Company	Philip Morris USA and the American Tobacco Company	"To be sure, a first-time user may quickly develop a 'tolerance' to the adversive effects of tobacco (e. g., nausea and throat irritation which some users experience)."	
B 15, N 4	36-37	1994	Philip Morris USA and the American Tobacco Company	Philip Morris USA and the American Tobacco Company	To be sure, there are mild pharmacological effects of nicotine, much in the same way that naturally occurring compounds in many products (e.g., caffeine, sugar) have a pharmacological effect."	
B 15, N 4	38	1994	Philip Morris USA and the American Tobacco Company	Philip Morris USA and the American Tobacco Company	"Nicotine is important to the taste and pleasure of smoking, but it is only one of many factors contributing to smoking behavior."	
B 15, N 4	42	1994	Philip Morris USA and the American Tobacco Company	Philip Morris USA and the American Tobacco Company	"Researchers have also found that the sensory responses in the throat associated with smoking are crucial factors in providing much of the immediate satisfaction from smoking."	
B 15, N 4	45-46	1994	Philip Morris USA and the American Tobacco Company	Philip Morris USA and the American Tobacco Company	"One researcher has stated that 'the physical actions of holding the cigarettes..., tamping the tobacco, striking matches, inhaling, and exhaling enables some persons to feel comfortable in stressful situations'.",	J. F. Greden *Caffeine and Tobacco Dependence*, 1985
B 15, N 5		1994	Juchatz, Wayne W.	R. J. Reynolds Tobacco Company	"R. J. Reynolds Tobacco Company ("Reynolds") is pleased to join in the written 'Submission of Philip Morris USA and the American Tobacco Company to the Drug Abuse Advisory Committee in connection with its meeting on August 2, 1994' dated July 29, 1994."	RJR joins submission by Philip Morris USA and the American Tobacco Company. Juchatz is the Executive Vice President of RJR.
B 15, N 6		1994	Byrd, G. D., J. H. Robinson, W. S. Caldwell and D. J. deBethizy	R. J. Reynolds Tobacco Company	"These data suggest that nicotine uptake is a function of individual smoking behavior within product design limits."	Abstract submitted by RJR to the Drug Abuse Advisory Committee.

Table 3 1 of 4

References to inhalation

in writings from within, or sponsored by, the tobacco industry

BINDER # ITEM #	PAGE	YEAR	AUTHOR (S)	COMPANY/GRANT AFFILIATION	QUOTE	COMMENT
B 16, N 1	150	1935	Flinn, Frederick B.	Philip Morris Grant	"If the smoker is of a nervous type, of the type that will consume a cigarette in a few minutes, the quantity of the combustion products in the inhaled smoke is much greater than that when it takes 10 minutes to smoke it."	underline added
B 16, N 1	153	1935	Flinn, Frederick B.	Philip Morris Grant	"The results from clinical show rather definitely that the combustion products of glycerin are more irritating to the throat...The glycerin cigarettes produced an irritation in the respiratory tract..."	
B 16, N 1	154	1935	Flinn, Frederick B.	Philip Morris Grant	"The combustion products of diethylene glycol cause only a slight irritation, if any, of the throat. There is some evidence that they may be beneficial where irritation is present."	
B 16, N 2	178	1939	Proetz, Arthur	Philip Morris Grant	"...it was arranged to study to habits of cigarette smokers unobserved...Some inhale deeply, some not at all."	Habits of cigarette smokers were studied to determine the effects of cigarette smoke upon oral mucosa.
B 16, N 3	717	1940	Mulinos, Michael G. & Israel Schulman	Philip Morris Grant	"Cigarette smoking is usually accompanied by deep inhalations of the smoke which is taken into the mouth, so that the inhaler absorbs more of the nicotine and other products of tobacco combustion..."	
B 16, N 3	717	1940	Mulinos, Michael G. & Israel Schulman	Philip Morris Grant	"...deep inhalations...exposes a greater mucous surface to the irritant properties of the smoke than would be the case if inhalation were not practiced."	
B 16, N 3	718	1940	Mulinos, Michael G. & Israel Schulman	Philip Morris Grant	"It may be that of the nicotine which was abstracted by the mucous membranes, more was absorbed from the lungs than from the mouth."	
B 16, N 4	237	1942	Haag, H. B. & P. S. Larson	American Tobacco Company Grant	Table 2: "..amount of nicotine eliminated by tobacco smokers" shows inhalers verses non-inhaler	Grantor (ATC) not noted on publication
B 16, N 5	21	1942	Weatherby, J. H.	American Tobacco Company	"The effects of tobacco on non-users were found to be much less marked than on habitual users. Apparently this is because nonsmokers do not inhale the smoke, as a rule, and consequently absorb less of the active constituents of the smoke."	Grantor not acknowledged in publication
B 16, N 5	24	1942	Weatherby, J. H.	American Tobacco Company	"The effects on blood pressure, pulse rate, and skin temperature of smoking one of these nicotine-free cigarettes (with inhalation) by an habitual smoker were similar in most respects to the effects of an ordinary cigarette when the smoke was *not inhaled*"	Grantor not acknowledged in the publication. Parentheses and italics in the original.
B 16, N 5	29	1942	Weatherby, J. H.	American Tobacco Company	"Many authors neglect to state whether or not inhalation was practiced by their subjects; yet the evidence indicates that this is of great importance in interpreting the results."	Grantor was not acknowledged in the publication

2048297348